[Bwrdd Iechyd Addysgu Powys / Powys Teaching Health Board]

National reference: CYM-25001

Local reference: PGD 0249

Community Pharmacy Common Ailment Service

Allergic Rhinitis

Patient Group Directions for the supply of azelastine nasal spray, fexofenadine tablets, sodium cromoglicate eye drops, fluticasone furoate nasal spray, fluticasone propionate nasal spray or mometasone nasal spray

in [**Powys Teaching Health Board**]

Operational from: 04 June 2025

Review date: 01 December 2027

Expiry date: 03 June 2028

Version number: v2.0

PGDs for the supply of oral and intranasal antihistamines, sodium cromoglicate eye drops and intranasal corticosteroids for the treatment of allergic rhinitis by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service.

Reference:	Allergic rhinitis PGDs
Version no:	2.0
Valid from:	04 June 2025
Review date:	01 December 2027
Expiry date:	03 June 2028

Welsh Medicines Advice Service has developed these PGDs for local authorisation

Those using these PGDs must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 3 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of these PGDs is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGDs.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THESE PGDs BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of these PGDs. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of a PGD should be addressed to: welshmedicines.information@wales.nhs.uk.

Change history:

Version number	Change details	Date
1.0	Original PGDs developed	22 December 2023
2.0	Allergic rhinitis PGDs combined into a booklet format and aligned with other national templates. Clinical content updated to align with approved allergic rhinitis monograph. New fexofenadine and sodium cromoglicate eye drop PGDs added. Patient advice section for the nasal sprays updated to include instructions for use and to refer to PIL for full instructions.	28 March 2025

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

These PGDs have been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when these PGDs are adopted by an organisation

PGD Development

Name	Designation	Signature
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB.	
Professional group reviewer – Adam Mackridge fexofenadine	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB and Chair of Community Pharmacy Clinical Advisory Group.	
Professional group reviewer – Carys James fluticasone furoate, fluticasone propionate	Community Pharmacy Facilitator, Cwm Taf Morgannwg UHB.	
Professional group reviewer – Emlyn Pritchard mometasone furoate	Head of Primary Care Medicines Management, Powys THB.	
Professional group reviewer – Amy David azelastine, sodium cromoglicate	Primary Care Pharmacist, Swansea Bay UHB.	
Expert reviewer – James Coulson	Clinical Director, All Wales Therapeutics and Toxicology Centre (AWTTC)	

These PGDs have been peer reviewed by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the WMAS PGD Policy and ratified by the All-Wales PGD Advisory Board.

Expert Panel – Community Pharmacy Clinical Advisory Group

Name	Designation
Adam Mackridge	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB and Chair of Community Pharmacy Clinical Advisory Group.
Louise Allen	Head of Community Pharmacy, Primary, Community and Intermediate Care. Cardiff and Vale UHB.
Amy David	Primary Care Pharmacist, Swansea Bay UHB.
Emlyn Pritchard	Head of Primary Care Medicines Management, Powys THB.
Jason Carroll	Pharmacy Team Leader – Community Services, Cwm Taf Morgannwg UHB.
Carys James	Community Pharmacy Facilitator, Cwm Taf Morgannwg UHB.

Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB.
Meryl Davies	Lead Antimicrobial Pharmacist Primary and Community Care, Health Protection Team, Public Health Wales.
Rachel James	Advanced Pharmacist, Community and Practice Development, Hywel Dda UHB.
Richard Evans	Community Pharmacy Advisor, Aneurin Bevan UHB.
Anna Burgess	Digital Lead Pharmacist, Welsh Medicines Advice Service, Cardiff and Vale UHB.

Date CPCAG approval of PGDs: 27 March 2025

Date All Wales PGD Advisory Board ratification: 04 April 2025

2. Contents

3. Organisational Authorisations

These PGDs are not legally valid until they have had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of these PGDs.

Powys Teaching Health Board authorises these PGDs for use by community pharmacies within its area that have been commissioned to provide the Common Ailments Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGDs.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Medical Director	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	5/6/2025
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	5/13/2025
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	5/1/2025
Senior Representative of Professional Group using PGD/Prescribing Advisor	Matthew Hicks	Signed by: Matthew Hicks 01F017E1634D479...	5/7/2025

Local enquiries regarding the use of these PGDs may be directed to:
[welshmedicines.information@wales.nhs.uk]
]

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to these PGDs. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of these PGDs.

Retention statement

The final authorised copy of this PGD should be kept by the authorising organisation completing section 3 for 8 years after the PGD expires if the PGD relates to adults only, and for 25 years after the PGD expires if the PGD relates to children only or adults and children.

Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

4. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacists must: ➢ be employed by or providing services on behalf of a pharmacy listed in the All-Wales Pharmacy Database (AWPD) for the Clinical Community Pharmacy Service. ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B. ➢ be familiar with the medicines and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Directions and associated resources (including the service specification and the clinical guidance document supporting the PGDs) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➢ be named in the All-Wales Pharmacy Database for the Common Ailment component of the Clinical Community Pharmacy Service. ➢ have met the training requirements for the service as published by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for azelastine, fexofenadine, fluticasone furoate, fluticasone propionate, and mometasone. ➢ have awareness of the adverse drug reactions associated with azelastine, fexofenadine, sodium cromoglicate, fluticasone furoate, fluticasone propionate, and mometasone. **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the Local Health Board in which area they are operating before working under its authority.**
Ongoing training and competency	Pharmacists must: ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in SmPC and BNF. ➢ be aware of any updates to relevant national and local guidelines. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of any training and competency assessments undertaken must be maintained.

PGD for the supply of azelastine hydrochloride 0.1% w/v (140 micrograms / dose) nasal spray

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Inclusion criteria	Azelastine hydrochloride 0.1% w/v (140 micrograms / dose) nasal spray can be given to individuals aged 6 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of symptoms associated with allergic rhinitis alone or in combination with intranasal corticosteroids (see PGD for fluticasone furoate, fluticasone propionate or mometasone furoate). AND ➢ informed consent has been given (patient, parent / guardian, carer).
Exclusion criteria[2] (continued over page)	Azelastine nasal spray should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, or presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital cellulitis. ➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome).

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with possible symptoms of meningitis (headache, photophobia AND fever). ➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with diagnostic uncertainty. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 6 years old. ➢ with symptoms thought to be medication-related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and NSAIDs, phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause, for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing e.g. if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed; in this case a referral to the GP would be necessary. ➢ who take contraindicated medicines (see drug interactions section for further detail) including: o isocarboxazid. o phenelzine. o tranylcypromine. ➢ with known hypersensitivity to azelastine hydrochloride 0.1% w/v (140 micrograms / dose) nasal spray or any of the excipients – see SmPC.
(continued over page)	

Exclusion criteria (continued)	➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for azelastine hydrochloride 0.1% w/v (140 micrograms / dose) nasal spray for full details of special warnings and precautions for use. **Pregnancy** Minimal systemic exposure is expected following intranasal administration due to the low dose and route of administration. **Breastfeeding** Minimal amounts expected in milk. Individuals should contact their health visitor, midwife or general practitioner if their baby: ➢ is not feeding as well as usual. ➢ is unsettled after feeding. ➢ is unusually sleepy. ➢ has a dry mouth. See also drug interactions section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist OR appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP if appropriate.
Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate pharmacist independent prescriber (PIP) should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Azelastine hydrochloride 0.1% w/v (140 microgram / dose) nasal spray. Each spray 0.14 mL contains 140 microgram azelastine.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	No.
Route / method of administration	Intranasal.
Dose and frequency of administration	**Adults and children aged 6 years and over:** ONE spray application in each nostril TWICE a day until symptoms resolve.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. Advise the individual to return if symptoms are persistent or treatment is ineffective after 4 weeks.
Quantity to be supplied	Appropriately labelled pack to provide treatment for maximum of THREE months at a time. **1 x 22 mL pack** provides 6 weeks of treatment at a dose of TWICE daily intranasal application. **1 x 20mL pack** provides 5 weeks of treatment at a dose of TWICE daily intranasal application.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions (continued over page)	The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. ➢ The SmPC for azelastine nasal spray states no specific interactions have been studied. ➢ The BNF states since systemic absorption can follow topical application, the possibility of interactions with topical azelastine should be borne in mind: **Contraindicated** ➢ Isocarboxazid, phenelzine, tranylcypromine – these are predicted to increase the risk of antimuscarinic adverse effects when given alongside azelastine. Manufacturer advises avoid.

Drug interactions (continued)	**Caution** ➢ Betahistine – azelastine is predicted to decrease the effects of betahistine.
Identification & management of adverse reactions	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body). The following side effects have been reported by individuals taking azelastine: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients) ➢ Bitter taste: this may be experienced after administration (often due to incorrect method of application, namely tilting the head too far backwards during administration) which in rare cases may lead to nausea. **Uncommon** (affecting between 1 in 100 and 1 in 1000 patients) ➢ Mild, transient irritation of the inflamed nasal mucosa may occur with symptoms such as: o stinging. o itching. o sneezing. o epistaxis. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or parent / carer advice / follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, they can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ to read the PIL before taking the medication.

Patient or parent / carer advice / follow up (continued)	➢ to visit the NHS website on allergic rhinitis for more information. ➢ if fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with a GP. **Directions for use** Refer to the PIL for full instructions. ➢ Remove the protective cap. ➢ Before first use, squeeze down the collar several times until an even spray emerges. The spray is now ready to use. Correct technique is very important when using nasal sprays to give the best chance of a satisfactory response to the medication. ➢ Blow nose. ➢ Spray once into each nostril keeping head upright. Do not tilt head backwards. ➢ Wipe the pump nozzle and replace the protective cap.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the nasal spray supplied in the hand-held maternity record (if available).

PGD for the supply of fexofenadine 30 mg and 120 mg tablets

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service.
Inclusion criteria	Fexofenadine tablets can be given to individuals aged 6 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of symptoms associated with allergic rhinitis alone or in combination with intranasal corticosteroids (see PGD for fluticasone furoate, fluticasone propionate or mometasone furoate). AND ➢ informed consent has been given (patient, parent / guardian, carer).
Exclusion criteria[3] (continued over page)	Fexofenadine tablets should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, or presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital or orbital cellulitis. ➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome).

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with possible symptoms of meningitis (headache, photophobia AND fever). ➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with diagnostic uncertainty. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 6 years old. ➢ with symptoms thought to be medication-related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and NSAIDs, phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause, for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing, e.g. if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed; in this case a referral to the GP would be necessary. ➢ who are pregnant, suspected of being pregnant or think they could be pregnant. ➢ who are currently breastfeeding. ➢ with known severe or chronic hepatic disease. ➢ with known severe or chronic kidney disease. ➢ with known hypersensitivity to fexofenadine tablets or any of the excipients – see SmPC.
(continued over page)	

Exclusion criteria (continued)	➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for fexofenadine for full details of special warnings and precautions for use. **Sedation** Fexofenadine is a non-sedating antihistamine causing less sedation and psychomotor impairment than the older antihistamines, but it can still occur. Sedation is generally minimal but if taken concomitantly with other sedating medicines or alcohol, this side effect may be enhanced. It may affect their ability to drive. **Cardiovascular disease** Advise individuals with history of or ongoing cardiovascular disease that antihistamines as a class of medicines have been associated with adverse reactions such as tachycardia and palpitations. See drug interactions section below for additional cautions.
Action to be taken if the individual is excluded or declines treatment	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist OR appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP or a community Pharmacist independent prescriber (PIP) if appropriate.
Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Fexofenadine 30 mg tablet. Fexofenadine 120 mg tablet.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	No.
Route / method of administration	Oral. Do not take indigestion remedies 2 hours before or after taking fexofenadine. Swallow whole, do not chew.
Dose and frequency of administration	**For children aged 6 years to 11 years** **Fexofenadine 30 mg tablets** ONE tablet (30 mg) to be taken TWICE daily. **For adults and children aged 12 years and above** **Fexofenadine 120 mg tablets** ONE tablet (120 mg) to be taken ONCE daily before a meal.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. Advise the individual to return if symptoms are persistent or treatment is ineffective after 4 weeks.
Quantity to be supplied	Appropriately labelled packs to provide treatment for maximum of THREE months at a time. 3 x 60 tablet (30 mg) pack. 3 x 30 (120 mg) tablet pack.
Storage	Medicines must be stored securely and in accordance with the product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions (continued over page)	The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Cautions** ➢ Antacids containing magnesium and aluminium may reduce the

Drug interactions (continued)	absorption of fexofenadine. Avoid concomitant use. It is advisable to leave 2 hours between administration of fexofenadine and antacids containing aluminium and magnesium. ➢ Erythromycin and ketoconazole may increase levels of fexofenadine. ➢ Apalutamide reduces exposure to fexofenadine. ➢ Betahistine levels may be decreased if fexofenadine is taken concomitantly. Advise the individual to monitor their labyrinthine symptoms (vertigo, dizziness, nausea and vomiting). ➢ Any concomitant medicine that can cause sedation. ➢ Grapefruit juice, apple juice, orange juice reduces the exposure to fexofenadine.
Identification & management of adverse reactions	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body). The following side effects have been reported by individuals taking fexofenadine: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ headache, drowsiness, dizziness. ➢ nausea. **Uncommon to very rare** (affecting between 1 in 100 and less than 1 in 10,000 patients): ➢ fatigue. **Unknown incidence**: ➢ diarrhoea. ➢ blurred vision. ➢ rash, urticaria, pruritis. ➢ tachycardia, palpitations. ➢ insomnia, nervousness, sleep disorders, nightmares, excessive dreaming. ➢ hypersensitivity reactions, angioedema, chest tightness, dyspnoea, flushing and anaphylaxis. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.

Patient or parent / carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, they can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on allergic rhinitis for more information. ➢ individuals should return to the pharmacy if symptoms do not improve after initial treatment as there are other options within CAS that may be suitable to try. ➢ to seek medical attention if they experience a fast heartbeat. **Delayed/missed doses** ➢ to take the medicine at the same time every day. Choose a time that is easy to remember. ➢ if they forget to take it, take it as soon as they remember unless its nearly time for the next dose. In this case, skip the missed dose and take the next dose at the usual time. ➢ do not take 2 doses to make up a forgotten dose. ➢ if their child is taking fexofenadine twice daily, they can give the dose if it's within 4 hours of when they should have had it. ➢ if it's more than 4 hours late, do not give the missed dose, instead wait until the next dose and carry on as normal. ➢ fexofenadine can sometimes cause dizziness or drowsiness. Advise that if they are affected, not to drive or operate machinery.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes.

PGD for the supply of sodium cromoglicate 2% w/v eye drops

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Inclusion criteria	Sodium cromoglicate 2% w/v eye drops can be supplied to individuals aged 6 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of eye symptoms associated with allergic conjunctivitis. ➢ for contact lens wearers with symptoms of allergic conjunctivitis AND they have been assessed as safe to continue by their optometrist. ➢ where informed consent has been given (patient, parent / guardian, carer).
Exclusion criteria[4]	Sodium cromoglicate eye drops should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital or orbital cellulitis. ➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome). ➢ with possible symptoms of meningitis (headache, photophobia AND fever).

(continued over page)

[4] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with diagnostic uncertainty. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 6 years old. ➢ with symptoms thought to be medication-related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and NSAIDs, phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing e.g. if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed; in this case a referral to the GP would be necessary. ➢ with known hypersensitivity to sodium cromoglicate 2% w/v eye drops or any of the excipients – see SmPC. ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.

Cautions (including relevant actions to be taken)	Please refer to the SmPC for sodium cromoglicate 2% w/v eye drops for full details of special warnings and precautions for use. **Pregnancy** Sodium cromoglicate 2% w/v eye drops can be used with caution if non-pharmacological measures are insufficient. Systemic absorption is minimal, and experience suggests there are no adverse effects on foetal development. **Breastfeeding** It is not known if sodium cromoglicate is excreted in breast milk following ophthalmic use, but based on its physiochemical properties it is considered unlikely. **Ability to drive and use machinery** Transient stinging or blurring of vision can occur on instillation of the drops. See patient advice section. **Benzalkonium chloride** As with other ophthalmic solutions containing benzalkonium chloride, soft contact lenses should not be worn during treatment period. Some formulations may contain benzalkonium chloride as a preservative which has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Use with caution in individuals with dry eye(s). Sodium cromoglicate 2% w/v preservative free formulations should be considered.
Action to be taken if the individual is excluded or declines treatment	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist or appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP if appropriate.
Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Sodium cromoglicate 2% w/v eye drops.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	No.
Route / method of administration	Topical ophthalmic.
Dose and frequency of administration	**Adults and children aged 6 years and over:** ONE drop into each eye up to FOUR times a day.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. If symptoms persist after 4 weeks or treatment is ineffective refer to WGOS registered optometrist.
Quantity to be supplied	Appropriately labelled packs to provide treatment for maximum of THREE months at a time. **1 x 13.5 mL pack** provides 4 weeks treatment.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Discard any remaining contents 4 weeks after opening. Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	No interaction studies have been performed. Advise individuals who use more than one type of eye drop, to wait 15 minutes between different preparations.
Identification & management of adverse reactions (continued over page)	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body).

Identification & management of adverse reactions (continued)	The following side effects have been reported by individuals taking sodium cromoglicate 2% w/v eye drops: ➢ transient stinging and burning may occur after instillation. This should only last for a short time and occur immediately after using the drops. ➢ other symptoms of local irritation have been reported rarely. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.
Patient or parent/ carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, they can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ benzalkonium chloride, the preservative used in the eye drops can sometimes cause eye irritation, symptoms of dry eye and may affect the tear film or surface of the eye. If their symptoms of itching, redness or swelling get worse, they should see a GP or community pharmacist. ➢ soft contact lenses should not be worn during the treatment period. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on allergic rhinitis for more information. **Directions for use** Refer to the PIL for full instructions. 1. Wash your hands before and after using the drops. 2. Remove the cap from the bottle. 3. Tilt the head back. 4. Use your finger to gently pull down your lower eyelid. 5. Hold the dropper over your eye, look up, and squeeze 1 drop into the lower eyelid without touching the eye. 6. Close your eye. 7. Wipe away any extra liquid with a clean tissue. 8. Repeat steps 3 to 7 in your other eye if appropriate. 9. Replace the cap back on the bottle.

Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the eye drops supplied in the hand-held maternity record (if available).

PGD for the supply of fluticasone furoate 27.5 micrograms / dose nasal spray

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Inclusion criteria	Fluticasone furoate 27.5 micrograms / dose nasal spray can be given to individuals aged 6 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of symptoms associated with allergic rhinitis alone or in combination with an intranasal or oral antihistamine. See PGD for azelastine or fexofenadine. AND ➢ where informed consent has been given (patient, parent / guardian, carer).
Exclusion criteria[5] (continued over page)	Fluticasone furoate 27.5 micrograms / dose nasal spray should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, or presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital or orbital cellulitis.

[5] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome). ➢ with possible symptoms of meningitis (headache, photophobia AND fever). ➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with diagnostic uncertainty. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 6 years old. ➢ with symptoms thought to be medication -related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and NSAIDs, phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing. For example, if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed; in this case a referral to the GP would be necessary. ➢ co-treated with CYP3A inhibitors, including ketoconazole, itraconazole, erythromycin, ritonavir and cobicistat-containing products as this is expected to increase the risk of systemic exposure of fluticasone and thus increased risk of side effects.

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Exclusion criteria (continued)	➢ currently taking oral, inhaled (high dose or multiple inhaled), potent topical or parenteral corticosteroids for any indication. ➢ who have undergone recent nasal surgery and healing is not complete. ➢ with an untreated nasal infection. ➢ with pulmonary tuberculosis. ➢ with a history of glaucoma or cataracts. ➢ with known hypersensitivity to fluticasone furoate or any of the excipients – see SmPC. ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for fluticasone furoate 27.5 micrograms / dose nasal spray for full details of special warnings and precautions for use. **Pregnancy and breastfeeding** Intranasal corticosteroids can be considered in pregnancy and or breast feeding if non-pharmacological measures are insufficient. They act locally and have lower systemic absorption (with low foetal exposure and negligible concentrations in milk) than oral preparations for allergic rhinitis. Intranasal corticosteroids pose no significant risk in pregnancy or breastfeeding. No specific monitoring is required. **Systemic effects of nasal corticosteroids** Systemic effects of intranasal corticosteroids are more likely if high doses are used and or used for prolonged periods of time. See adverse effects section. Individuals with confirmed or suspected immunosuppression should be warned about the risk of exposure to certain infections (e.g. chickenpox, measles) and the importance of obtaining medical advice if such exposure occurs.
Action to be taken if the individual is excluded or declines treatment (continued over page)	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist or appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record.

Action to be taken if the individual is excluded or declines treatment (continued)	➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP if appropriate.
Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Fluticasone furoate 27.5 micrograms / dose nasal spray.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. **Pregnancy and breastfeeding** The SmPC states that fluticasone furoate should only be considered if the benefits to the mother outweigh the possible risk to the foetus or child. The advice from the UK Teratology Information Service (UKTIS) and UK Drugs in Lactation Service (UKDILAS) states that intranasal corticosteroids should be considered if non-pharmacological measure are ineffective. They act locally and have lower systemic absorption compared to oral treatments. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. Any advice given should be documented in the consultation notes.
Route / method of administration	Intranasal.
Dose and frequency of administration	**Adults and children aged 12 years and over:** Initially: ➢ TWO spray applications in each nostril ONCE a day. Once symptoms are controlled, for maintenance, reduce dose to: ➢ ONE spray application in each nostril ONCE a day. Use the minimum effective dose to achieve control of symptoms. **Children aged 6 to 11 years:** The recommended starting dose is: ➢ ONE spray application in each nostril ONCE a day. If an adequate response at this dose is not achieved within 5-7 days, increase the dose to: ➢ TWO spray applications in each nostril ONCE a day. Once adequate control of symptoms is achieved, reduce dose to: ➢ ONE spray application in each nostril ONCE daily. Use the minimum effective dose to achieve control of symptoms.

Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. If control of symptoms is not achieved or symptoms are persisting after 4 weeks advise individual to see GP or pharmacist independent prescriber.
Quantity to be supplied	Appropriately labelled packs to provide treatment for maximum of THREE months at a time. **1 x 120 dose pack** provides TWO months treatment at a maintenance dose of ONE spray application in each nostril ONCE daily.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC. The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** Co-treatment with CYP3A inhibitors, including ketoconazole, itraconazole, erythromycin, ritonavir and cobicistat-containing products, is expected to increase the risk of systemic side-effects of fluticasone due to the increased risk of systemic exposure. The combination should be avoided.
Identification & management of adverse reactions (continued over page)	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body). **Systemic corticosteroid effects** The following systemic effects may occur particularly with high doses or prolonged treatment periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different preparations: ➢ Cushing's syndrome, Cushingoid features, adrenal suppression - very rarely the normal production of steroids in the body may be affected leading to a life-threatening situation. This risk may be higher in the following examples: those with endocrine disorders, the elderly, those

Identification & management of adverse reactions (continued)	who have an infection or those who are dehydrated. ➢ Growth retardation in children and adolescents. ➢ Cataract. ➢ Glaucoma. ➢ A range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). These effects are rare. **Visual disturbance** Instances of increased intraocular pressure have been reported following the use of intranasal corticosteroids. Individuals should be advised to visit an optician if they notice any changes in their eye(s), for example, blurred vision or other visual disturbances. The following side effects have been reported by individuals taking fluticasone furoate: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ headache. ➢ nasal ulceration. ➢ dyspnoea. ➢ epistaxis (generally mild to moderate in intensity. In adults and adolescents, incidence higher in longer-term use i.e. >6 weeks). **Uncommon** (affecting between 1 in 100 and 1 in 1000 patients): ➢ rhinalgia. ➢ nasal discomfort (including nasal burning, nasal irritation and nasal soreness). ➢ nasal dryness. **Very rare** (affecting less than in 1 in 10000 patients): ➢ nasal septum perforation. **Not known** (cannot be estimated from the available data): ➢ transient ocular changes including blurred vision. ➢ bronchospasm. ➢ growth retardation. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.

Patient or carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ the medicine should begin to relieve symptoms between 8 and 24 hours after the first dose. ➢ the full benefit of treatment may not be seen for up to 2 weeks. ➢ their symptoms should improve with continuous regular use. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ the nasal spray contains benzalkonium chloride. Advise the individual to see a GP if they develop symptoms of bronchospasm e.g. wheezing, coughing and shortness of breath. It may also cause oedema of the nasal mucosa in long term use. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on allergic rhinitis for more information. ➢ if fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with a GP. **Directions for use** Refer to the PIL for full instructions. **Preparing your nasal spray for use** Prior to first use and / or if you have left the cap off for 5 days or more and / or the device has not been used for 30 days or more, the nasal spray needs preparing. Preparing the nasal spray helps to make sure you always get the full dose of medicine. ➢ Shake the nasal spray bottle vigorously with the cap on for about 10 seconds. This is important as the contents are a thick suspension that becomes liquid when you shake it well. It will only spray when it becomes liquid. ➢ Remove the cap by squeezing firmly on the sides of the cap with your thumb and forefinger. ➢ Hold the nasal spray upright, then tilt and point the nozzle away from you. ➢ Press the button firmly all the way in. Do this at least 6 times until it releases a fine mist of spray into the air. The nasal spray is now ready for use. (continued over page)

Patient or carer advice / follow up (continued)	**How to use the nasal spray** Correct technique is very important when using nasal sprays to give the best chance of a satisfactory response to the medication. 1. Shake the nasal spray bottle vigorously. 2. Remove the dust cap. 3. Blow your nose gently to clear your nostrils, then tilt your head forward a little. 4. Place the nozzle in one of your nostrils. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose. 5. Start to breathe in slowly through your nose and at the same time press down firmly on the button of the bottle. This will release a spray of fluticasone furoate. 6. Take the nozzle out and breathe out through your mouth. 7. Repeat steps 4 to 6 if more than one spray is required into the same nostril. 8. Repeat steps 4-7 to treat the other nostril. 9. Replace the cap on the nasal spray.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the nasal spray supplied in the hand-held maternity record (if available).

PGD for the supply of fluticasone propionate 50 micrograms / dose nasal spray

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Inclusion criteria	Fluticasone propionate 50 micrograms / dose nasal spray can be given to individuals aged 4 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of symptoms associated with allergic rhinitis alone or in combination with an intranasal or oral antihistamine. See PGD for azelastine or fexofenadine. AND ➢ where informed consent has been given (patient, parent/guardian, carer).
Exclusion criteria[6] (continued over page)	Fluticasone propionate 50 micrograms / dose nasal spray should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, or presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital or orbital cellulitis.

[6] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome). ➢ with possible symptoms of meningitis (headache, photophobia AND fever). ➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with diagnostic uncertainty. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 4 years old. ➢ with symptoms thought to be medication-related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and NSAIDs, phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing. For example, if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed; in this case a referral to the GP would be necessary. ➢ co-treated with CYP3A inhibitors, including ketoconazole, itraconazole, erythromycin, ritonavir and cobicistat-containing products as this is expected to increase the risk of systemic exposure of fluticasone and thus increased risk of side effects. ➢ currently taking oral, inhaled (high dose or multiple inhaled), potent topical or parenteral corticosteroids for any indication. ➢ who have undergone recent nasal surgery and healing is not complete. ➢ with an untreated nasal infection.
(continued over page)	

Exclusion criteria (continued)	➢ with pulmonary tuberculosis. ➢ with a history of glaucoma or cataracts. ➢ with known hypersensitivity to fluticasone propionate 50 micrograms / dose nasal spray or any of the excipients – see SmPC. ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for fluticasone propionate 50 micrograms / dose nasal spray for full details of special warnings and precautions for use. **Pregnancy and breastfeeding** Intranasal corticosteroids can be considered in pregnancy and or breast feeding if non-pharmacological measures are insufficient. They act locally and have lower systemic absorption (with low foetal exposure and negligible concentrations in milk) than oral preparations for allergic rhinitis. Intranasal corticosteroids pose no significant risk in pregnancy or breastfeeding. No specific monitoring is required. **Systemic effects of nasal corticosteroids** Systemic effects of intranasal corticosteroids are more likely if high doses are used and or used for prolonged periods of time. See adverse effects section. Individuals with confirmed or suspected immunosuppression should be warned about the risk of exposure to certain infections (e.g. chickenpox, measles) and the importance of obtaining medical advice if such exposure occurs.
Action to be taken if the individual is excluded or declines treatment	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist or appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP if appropriate.

Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Fluticasone propionate 50 micrograms / dose nasal spray.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. **Pregnancy and breastfeeding.** The SmPC states that fluticasone propionate should only be considered if the benefits to the mother outweigh the possible risk to the foetus or child. The advice from the UK Teratology Information Service (UKTIS) and UK Drugs in Lactation Service (UKDILAS) states that intranasal corticosteroids should be considered if non-pharmacological measure are ineffective. They act locally and have lower systemic absorption compared to oral treatments. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. Any advice given should be documented in the consultation notes.
Route / method of administration	Intranasal.
Dose and frequency of administration (continued over page)	For full therapeutic benefit regular usage is essential. Maximum relief may not be obtained until after 3 to 4 days of treatment. Use the minimum effective dose to achieve control of symptoms. **Adults and children aged 12 years and over:** Initially: ➢ TWO spray applications in each nostril ONCE a day, preferably in the morning. ➢ In some cases, TWO sprays into each nostril TWICE a day may be required. Once symptoms are controlled, for maintenance, reduce dose to: ➢ ONE spray application in each nostril ONCE a day. ➢ If symptoms recur, the dosage may be increased accordingly. The maximum daily dose should not exceed FOUR sprays into each nostril. **Children aged of 4 to 11 years:** The recommended starting dose is: ➢ ONE spray application in each nostril ONCE a day, preferably in the morning. ➢ In some cases, ONE spray into each nostril TWICE a day may be required.

Dose and frequency of administration (continued)	Once adequate control of symptoms is achieved, reduce dose to: ➢ ONE spray application in each nostril ONCE daily. The maximum daily dose should not exceed TWO sprays into each nostril.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. If control of symptoms is not achieved or symptoms are persisting after 4 weeks advise individual to see GP or pharmacist independent prescriber.
Quantity to be supplied	Appropriately labelled packs to provide treatment for maximum of THREE months at a time. **1 x 150 dose pack** provides at least 4 weeks treatment for the initial dose of TWO applications in each nostril ONCE daily.
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC. The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** ➢ Co-treatment with CYP3A inhibitors, including ketoconazole, itraconazole, erythromycin, ritonavir and cobicistat-containing products, is expected to increase the risk of systemic side-effects of fluticasone due to the increased risk of systemic exposure. The combination should be avoided.
Identification & management of adverse reactions (continued over page)	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body). **Systemic corticosteroid effects** The following systemic effects may occur particularly with high doses or prolonged treatment periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different preparations:

Identification & management of adverse reactions (continued)	➢ Cushing's syndrome, Cushingoid features, adrenal suppression - very rarely the normal production of steroids in the body may be affected leading to a life-threatening situation. This risk may be higher in the following examples: those with endocrine disorders, the elderly, those who have an infection or those who are dehydrated. ➢ growth retardation in children and adolescents. ➢ cataract. ➢ glaucoma. ➢ a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). These effects are rare. **Visual disturbance** Instances of increased intraocular pressure have been reported following the use of intranasal corticosteroids. Individuals should be advised to visit an optician if they notice any changes in their eye(s), for example, blurred vision or other visual disturbances. The following side effects have been reported by individuals taking fluticasone propionate: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ epistaxis ➢ headache. ➢ unpleasant taste. ➢ unpleasant smell. ➢ nasal dryness, nasal irritation. ➢ throat dryness, throat irritation. **Rare to very rare** (up to or less than in 1 in 10,000 patients): ➢ glaucoma (following prolonged treatment). ➢ raised intraocular pressure (following prolonged treatment). ➢ cataract (following prolonged treatment). ➢ nasal septum perforation. **Not known** (cannot be estimated from the available data): ➢ nasal ulceration. ➢ blurred vision. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.

Patient or carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, they can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ the medicine should begin to relieve symptoms 6-8 hours after the first dose. ➢ maximum relief may not be obtained until after 3-4 days of treatment. ➢ for full therapeutic benefit regular usage is essential. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ the nasal spray contains benzalkonium chloride. Advise the individual to see a GP if they develop symptoms of bronchospasm e.g. wheezing, coughing and shortness of breath. It may also cause oedema of the nasal mucosa in long term use. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on allergic rhinitis for more information. ➢ if fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with a GP. **Directions for use** Refer to the PIL for full instructions. **Preparing your nasal spray for use** Prior to first use or if the device has not been used for a few days, the nasal spray needs to be primed. Preparing the nasal spray helps to make sure you always get the full dose of medicine. This can be done by pumping the spray a few times until a fine mist is produced. ➢ Hold the nasal spray upright, making sure it is pointing away from you. Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle. ➢ Keep your thumb still, press down with your fingers to pump the spray. ➢ Repeat this a few times until a fine mist of spray is released into the air. The nasal spray is now ready for use.

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Patient or carer advice / follow up (continued)	**How to use the nasal spray** Correct technique is very important when using nasal sprays to give the best chance of a satisfactory response to the medication. 1. Shake the nasal spray bottle and remove the dust cap. 2. Blow your nose gently to clear your nostrils, then tilt your head forward a little. 3. Place one finger on your nose to close one nostril and put the nozzle in your other nostril. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose. 4. Start to breathe in slowly through your nose and at the same time press down firmly on the collar of the bottle. This will release a fine mist of fluticasone propionate into your nostril. 5. Take out the nozzle and breathe out through your mouth. Repeat steps 4 to 6 if more than one spray is required into the same nostril or steps 3 to 6 to treat the other nostril. 6. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the nasal spray supplied in the hand-held maternity record (if available).

PGD for the supply of mometasone furoate 50 micrograms / dose nasal spray

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For the treatment of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Inclusion criteria	Mometasone furoate 50 micrograms / dose nasal spray can be given to individuals aged 3 years and over in accordance with the All Wales Common Ailments Service Formulary: ➢ for the relief of symptoms associated with allergic rhinitis alone or in combination with an intranasal or oral antihistamine. See PGD for azelastine or fexofenadine. AND ➢ where informed consent has been given (patient, parent / guardian, carer).
Exclusion criteria[7] (continued over page)	Mometasone furoate 50 micrograms / dose nasal spray should not be given to individuals: ➢ if they have the following eye symptoms which might suggest acute glaucoma, keratitis/iritis, corneal ulceration, or presence of pseudo membrane: o marked redness in the affected eye(s) along with headache, any eye pain, and / or photophobia. o halos around lights, flashing lights/wavy lines, nausea/vomiting. o change in visual acuity (unrelated to watering or tearing). ➢ unable to open the eye or keep it open. ➢ with pupils that look unusual. ➢ who wear contact lenses and present with eye symptoms - individuals should also be advised not to wear contact lenses until they have been assessed and further advice obtained from their optometrist (if same-day assessment by the optometrist is not feasible, the individual should be referred to eye casualty and should be advised to take their contact lenses with them as special diagnostic tests may be required). ➢ with a history of trauma (mechanical, chemical or ultraviolet), or possible foreign body. ➢ with copious, rapidly progressive discharge from the eye. ➢ with a possible herpes virus infection (crops of vesicles, ulcers or pustules present on the eyelid or around the eye). ➢ with suspected periorbital or orbital cellulitis.

[7] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Exclusion criteria (continued)	➢ with suspicion of an undiagnosed systemic disease (rheumatoid arthritis or Sjogren's syndrome). ➢ with possible symptoms of meningitis (headache, photophobia AND fever). ➢ with suspected atopic keratoconjunctivitis (chronic symptoms with a history of asthma, eczema, severe itching, tearing and swelling). ➢ with suspected vernal keratoconjunctivitis (severe itching, copious fibrinous discharge, worse in the spring). ➢ with severe or treatment resistant allergic conjunctivitis. ➢ with diagnostic uncertainty. ➢ with unilateral symptoms, blood stained or discoloured nasal discharge, recurrent epistaxis, facial or nasal pain or tenderness or anosmia. ➢ with evidence of nasal obstruction or structural abnormality (deviated nasal septum). ➢ with suspected infective rhinitis or infective sinusitis. ➢ with loss of asthma control or they have lower respiratory tract symptoms. ➢ aged less than 3 years old. ➢ with symptoms thought to be medication-related including recreational drugs. For example, decongestants (rebound congestion), alpha-blockers, ACE inhibitors, beta-blockers, aspirin, chlorpromazine and phosphodiesterase inhibitors and cocaine as the individual will need a medication review. ➢ with symptoms thought to be due to a non-allergic cause for example: o chemical (perfumes, tobacco, smoke, odours). o physical (changes in temperature, humidity or with exercise). o endocrine (pregnancy, oral contraceptives, hypothyroidism). o food and drink (alcohol, spicy foods, sulphites). o systemic (defect in mucus production). o structural (aging). ➢ with symptoms that are persistent or refractory despite optimal treatment. ➢ who require allergy testing. For example, if the individual has trialled a number of treatments with unsuccessful results and may have an atopic history / family history of allergies whereby further investigation may be needed. In this case a referral to the GP would be necessary. ➢ co-treated with CYP3A inhibitors, including cobicistat-containing products as this is expected to increase the risk of systemic side effects. ➢ currently taking oral, inhaled (high dose or multiple inhaled), potent topical or parenteral corticosteroids for any indication. ➢ who have undergone recent nasal surgery and healing is not complete. ➢ with an untreated nasal infection.
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Exclusion criteria (continued)	➢ with pulmonary tuberculosis. ➢ with a history of glaucoma or cataracts. ➢ with known hypersensitivity to mometasone furoate nasal spray or any of the excipients – see SmPC. ➢ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it. ➢ who are unable to administer or use the product effectively themselves or who do not have a parent / guardian / carer to administer or apply the medication for them. ➢ who do not agree to share relevant clinical information.
Cautions (including relevant actions to be taken)	Please refer to the SmPC for mometasone furoate 50 micrograms / dose nasal spray for full details of special warnings and precautions for use. **Pregnancy and breastfeeding** Intranasal corticosteroids can be considered in pregnancy and or breast feeding if non-pharmacological measures are insufficient. They act locally and have lower systemic absorption (with low foetal exposure and negligible concentrations in milk) than oral preparations for allergic rhinitis. Intranasal corticosteroids pose no significant risk in pregnancy or breastfeeding. No specific monitoring is required. **Systemic effects of nasal corticosteroids** Systemic effects of intranasal corticosteroids are more likely if high doses are used and or used for prolonged periods of time. See adverse effects section. Individuals with confirmed or suspected immunosuppression should be warned about the risk of exposure to certain infections (e.g. chickenpox, measles) and the importance of obtaining medical advice if such exposure occurs.
Action to be taken if the individual is excluded or declines treatment	➢ If an individual with eye symptoms meets the exclusion criteria, refer to a WGOS registered optometrist or appropriate practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. See the allergic rhinitis section of the All Wales Common Ailments Service Formulary. ➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines, advise of the consequences of not receiving treatment and document the advice given and details of any referral made and their (patient, parent / carer or guardian) intended actions. ➢ If appropriate, individuals may be offered a suitable alternative treatment or provided with advice and symptomatic treatment from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to a GP if appropriate.

Further advice	If there is any doubt about the administration of the medication or individuals' fitness or suitability to receive the medication, a doctor or appropriate PIP should be consulted. ➢ Refer to SmPC, BNF and the All Wales Common Ailments Service.

2. Description of Treatment

Name, strength & formulation of drug	Mometasone furoate 50 micrograms / dose nasal spray.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Yes. **Pregnancy and breastfeeding.** The SmPC states that mometasone furoate should only be considered if the benefits to the mother outweigh the possible risk to the foetus or child. The advice from the UK Teratology Information Service (UKTIS) and UK Drugs in Lactation Service (UKDILAS) states that intranasal corticosteroids should be considered if non-pharmacological measure are ineffective. They act locally and have lower systemic absorption compared to oral treatments. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. Any advice given should be documented in the consultation notes.
Route / method of administration	Intranasal.
Dose and frequency of administration	For full therapeutic benefit, regular usage is essential. Maximum relief may not be achieved in the first 48 hours of treatment. Use the minimum effective dose to achieve control of symptoms. **Adults and children aged 12 years and over:** Initially: ➢ TWO spray applications in each nostril ONCE a day. ➢ In some cases, FOUR sprays into each nostril ONCE a day can be used if symptoms are inadequately controlled. Once symptoms are controlled, for maintenance, reduce dose to: ➢ ONE spray application in each nostril ONCE a day. The maximum daily dose should not exceed FOUR sprays in each nostril. **Children aged 3 to 11 years:** ➢ ONE spray application in each nostril ONCE a day.

Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above. If treatment provides adequate symptom control, advise the individual to continue treatment until they are no longer likely to be exposed to the suspected allergen. If control of symptoms is not achieved or symptoms are persisting after 4 weeks advise individual to see GP or pharmacist independent prescriber.
Quantity to be supplied	Appropriately labelled packs to provide treatment for maximum of THREE months at a time. **1 x 140 dose pack** provides TWO months treatment at a dose of ONCE daily application (maintenance).
Storage	Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	➢ Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC. The following list of interactions is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF. **Contraindicated** ➢ Co-treatment with CYP3A inhibitors, including ketoconazole, itraconazole, erythromycin, ritonavir and cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided.
Identification & management of adverse reactions (continued over page)	Advise the individual that if any of the following side effects occur to **discontinue treatment immediately and contact the emergency department or dial 999**: ➢ Allergic reactions such as sudden wheeziness, difficulty with breathing, speaking and swallowing. ➢ Swelling of the eyelids, face or lips. ➢ Rash or itching (especially affecting your whole body). **Systemic corticosteroid effects** The following systemic effects may occur particularly with high doses or prolonged treatment periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different preparations: ➢ Cushing's syndrome, Cushingoid features, adrenal suppression - very rarely the normal production of steroids in the body may be affected leading to a life-threatening situation. This risk may be higher in the following examples: those with endocrine disorders, the elderly, those who have an infection or those who are dehydrated.

Identification & management of adverse reactions (continued)	➢ growth retardation in children and adolescents. ➢ cataract. ➢ glaucoma. ➢ a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). These effects are rare. **Visual disturbance** Instances of increased intraocular pressure have been reported following the use of intranasal corticosteroids. Individuals should be advised to visit an optician if they notice any changes in their eye(s), for example, blurred vision or other visual disturbances. The following side effects have been reported by individuals taking mometasone furoate: **Very common to common** (affecting between 1 in 10 and 1 in 100 patients): ➢ epistaxis (less likely to be seen in doses used for allergic rhinitis treatment). ➢ pharyngitis. ➢ upper respiratory tract infection. ➢ headache. ➢ nasal burning. ➢ nasal irritation. ➢ nasal ulceration. **Not known** (cannot be estimated from the available data): ➢ glaucoma (following prolonged treatment). ➢ increased intraocular pressure. ➢ cataracts, blurred vision. ➢ nasal septum perforation. ➢ taste and smell disturbances. ➢ hypersensitivity including anaphylactic reactions, angioedema, bronchospasm and dyspnoea. N.B. detailed lists of adverse reactions are available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.

Patient or carer advice / follow up	Supply the marketing authorisation holder's patient information leaflet (PIL). Inform the individual or their parent or carer: ➢ if they have an eye problem, including those that need urgent attention, can access free eye examinations by visiting a WGOS registered optometrist practice. A list of registered practices is available at WGOS 2 – Examination for Urgent Eye Problems and NHS 111 Wales. ➢ for full therapeutic benefit regular usage is essential. ➢ in some patients, this medicine should begin to relieve symptoms 12 hours after the first dose. ➢ full benefit of treatment may not be seen for up to two days. ➢ if they are concerned about side effects, to talk to their doctor, or pharmacist or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme; this includes any possible side effects not listed in the PIL. ➢ the nasal spray contains benzalkonium chloride. Advise the individual to see a GP if they develop symptoms of bronchospasm e.g. wheezing, coughing and shortness of breath. It may also cause oedema of the nasal mucosa in long term use. ➢ to seek medical advice from an appropriate practitioner if their condition deteriorates and / or they become systemically unwell. ➢ to read the PIL before taking the medication. ➢ to visit the NHS website on allergic rhinitis for more information. ➢ if fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with a GP. **Directions for use** Refer to the PIL for full instructions. **Preparing your nasal spray for use** The pump spray will need priming prior to first use. This can be done by pumping the spray 10 times until a fine mist is produced: ➢ Gently shake the bottle. ➢ Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle. ➢ Keep the thumb still and press down with your fingers to pump the spray holding the nozzle away from you. If the nasal spray has not been used for 14 days or longer it should be re-primed by pumping the spray twice until a fine mist is produced. **How to use the nasal spray** Correct technique is very important when using nasal sprays to give the best
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Patient or carer advice / follow up (continued)	chance of a satisfactory response to the medication. 1. Shake the bottle gently. 2. Remove the dust cap. 3. Blow your nose gently. 4. Hold the bottle with your index finger and middle finger either side of the nozzle and your thumb on the base of the bottle. Place one finger on your nose to close one nostril and put the nozzle in your other nostril. Tilt your head forward and keep the bottle upright. Start to breathe in slowly through your nose and at the same time press down firmly on the collar of the bottle with your finger, which releases a spray of mometasone furoate. 5. Breathe out through your mouth. Repeat step 4 if more than one spray is required into the same nostril. Remove the nozzle from the nostril and breathe out through your mouth. 6. Repeat steps 4 to 5 for the other nostril. 7. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap.
Records	The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred into Choose Pharmacy as soon as practically possible following the consultation. If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. For pregnant women record the nasal spray supplied in the hand-held maternity record (if available).

Appendices

Appendix A: *Key references*

- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. September 2024 Available from: https://awttc.nhs.wales [accessed 31 December 2024].
- British National Formulary (BNF) – current edition. Available from: https://bnf.org.uk [accessed 31 December 2024].
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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Directions for the supply of: azelastine hydrochloride 0.1% w/v (140 micrograms/dose), fluticasone furoate 27.5 micrograms/dose, fluticasone propionate 50 micrograms/dose and mometasone 50 micrograms/dose nasal sprays, fexofenadine 30 mg and 120 mg tablets and sodium cromoglicate 2% w/v eye drops by community pharmacists under the Clinical Community Pharmacy Service: Common Ailments Service (allergic rhinitis) commissioned by [Powys Teaching Health Board]

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD **confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct**. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct

Name of registered pharmacist	Signature	GPhC number	Date

This authorisation sheet should be kept serving as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the organisational authorisation section.