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Patient Group Direction

For the supply of

Fluticasone propionate 50 micrograms/dose nasal spray

By registered community pharmacists providing the

NHS Wales Clinical Community Pharmacy Service for

the treatment of symptoms of allergic rhinitis

in [Powys Teaching Health Board]

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

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PGD for the supply of fluticasone propionate 50 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis by pharmacists delivering the Common Ailment Service component of the Clinical Community Pharmacy Service

Reference:	Fluticasone propionate 50 micrograms/dose nasal spray PGD
Version no:	1.0
Valid from:	1st July 2023
Review date:	31st March 2026
Expiry date:	30th June 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 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 this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

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

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

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

Change history:

Version number	Change details	Date
1.0	Original PGD template developed	20th February 2023

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

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Position	Designation
Alya Al-Affan	Main author	Formulary and PGD Lead for the Common Ailments Service, Welsh Medicines Advice Service, Cardiff and Vale UHB
Adam Mackridge	CPCAG reviewer	Chair of Community Pharmacy Clinical Advisory Group (CPCAG) and Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB
Louise Allen	CPCAG reviewer	Head of Community Pharmacy, Primary, Community and Intermediate Care. Cardiff and Vale UHB
Rachel James	CPCAG reviewer	Advanced Pharmacist, Community and Practice Development, Hywel Dda UHB
Manjeet Singh	Medical Reviewer	Consultant in Acute Care, Aneurin Bevan UHB

Date CPCAG approval of PGD: 13th June 2023

2. Organisational authorisations

The PGD is not legally valid until it has 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 the PGD.

Powys Teaching Health Board authorises this PGD 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 PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	9/7/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	9/12/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	9/12/2023
Senior Pharmacist Lead for Community Pharmacies PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	9/7/2023

Local enquiries regarding the use of this PGD 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 this PGD. 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 this PGD.

3. 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 medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) 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 set out by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for fluticasone propionate 50 micrograms/dose nasal spray. ➢ have awareness of the adverse drug reactions associated with fluticasone propionate 50 micrograms/dose nasal spray. **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 the 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 training and competence must be maintained in the individual's personal file.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of symptoms of allergic rhinitis in accordance with the community pharmacy Common Ailment Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Fluticasone propionate 50 micrograms/dose nasal spray can be supplied to individuals aged 4 years and over, presenting with symptoms of seasonal allergic or perennial rhinitis and in which initial drug treatment from the formulary options have been ineffective, or for moderate-to-severe persistent symptoms and: ➢ they have no contraindications to fluticasone propionate 50 micrograms/dose nasal spray – see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion[2]	Fluticasone propionate 50 micrograms/dose nasal spray should not be supplied: ➢ to individuals who present with red flag symptoms including: o fever o shortness of breath o recurrent epistaxis o nasal pain ➢ if infective rhinitis is suspected e.g. high fever, extreme tenderness around the eyes or nose. ➢ in the presence of untreated localised infection involving the nasal mucosa, such as herpes simplex. ➢ to individuals who have experienced recent nasal surgery or trauma until healing has occurred (due to the inhibitory effect of corticosteroids on wound healing).

[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.

(continued over page)	➢ to individuals with active or quiescent tuberculosis infections of the respiratory tract, or in untreated fungal, bacterial or systemic viral infections. ➢ to individuals receiving corticosteroids who are potentially immunocompromised. ➢ if nasal septum perforation, nasal obstruction or new nasal abnormality is present. ➢ if symptoms are thought to be medication-related e.g. decongestants (rebound congestion), alpha-blockers, ACE
Criteria for exclusion (continued)	inhibitors, beta-blockers, aspirin and NSAIDs as the individual will need a medication review. ➢ if symptoms are thought to be due to a non-allergic cause e.g. chemical, physical, endocrine, food and drink, systemic, structural. ➢ if symptoms persist and are refractory to treatment despite using the steroid nasal spray correctly for 4 weeks. ➢ if allergy testing may be needed - 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. ➢ if diagnosis is uncertain. ➢ in individuals being co-treated with CYP3A inhibitors, including ketoconazole, 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. ➢ pregnancy. ➢ breastfeeding. ➢ to individuals 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.

	➢ to individuals 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. ➢ if individual does not agree to share relevant clinical information.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for fluticasone propionate 50 micrograms/dose nasal spray for full details of special warnings and precautions for use. ➢ Systemic effects of nasal corticosteroids may occur. These are more likely to occur with high dose nasal corticosteroids used for prolonged periods. Potential systemic effects may include: o Cushing's syndrome o cushingoid features
Cautions (including relevant actions to be taken) (continued)	o 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. o growth retardation in children and adolescents o cataract o glaucoma o a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children); these effects are rare ➢ Instances of increased intraocular pressure have been reported following the use of intranasal corticosteroids. Individuals should be advised to visit an optician they notice any changes in their eye(s), for example, blurred vision or other visual disturbances. ➢ The nasal spray contains benzalkonium chloride which may cause bronchospasm. It may also cause oedema of the nasal mucosa in long term use.
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record.

	➢ If the individual declines, record the reason and advise of the consequences of not receiving treatment. Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. ➢ If appropriate, patients may be offered a suitable alternative to fluticasone propionate 50 micrograms/dose nasal spray from the All Wales Common Ailments Service Formulary. Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	➢ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.

5. Description of treatment

Name, strength & formulation of drug	Fluticasone propionate 50 micrograms/dose nasal spray
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No
Off-label use	No
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, preferably in the morning. In some cases, two sprays into each nostril twice a day may be required. Once symptoms are controlled, for maintenance, dose reduce to: ONE spray application in each nostril ONCE a day. The maximum daily dose should not exceed four sprays into each nostril. **Children between the ages of 4 and 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. <u>Once adequate control of symptoms is achieved, dose reduction to:</u> ONE spray application in each nostril ONCE daily is recommended. The maximum daily dose should not exceed 2 sprays into each nostril.
Duration of treatment	This PGD only allows for the duration stated below.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for FOUR weeks. 1 x 150 dose pack to provide 4 weeks treatment at a dose of ONCE daily application.
Drug interactions (continued over page)	➢ Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC.
Drug interactions (continued)	**Contraindication** ➢ Co-treatment with CYP3A inhibitors, including ketoconazole, 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 unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. Prior to offering treatment to an individual, the SmPC and the BNF should be referred to in order to check there are no changes regarding the interaction status of fluticasone.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF. Please refer to these resources to check there has been no change to the lists below. If the patient experiences any of the following they must discontinue treatment: ➢ difficulty breathing or swallowing ➢ swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) ➢ severe itching of the skin, with a rash or raised lumps, hives or

(continued over page)	blisters The following side effects have been reported as: Very common to common (affecting less than 1 in 10 or 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 1 in 10000 patients) ➢ Glaucoma (following prolonged treatment) ➢ Raised intraocular pressure (following prolonged treatment)
Identification & management of adverse reactions (continued)	➢ 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). In some patients, this medicine should begin to relieve symptoms 12 hours after the first dose, however full benefit of treatment may not be obtained until after 3 to 4 days of treatment.

(continued over page)	**Directions for use** <u>Preparing your nasal spray for use</u> Prior to first use or if the device has not been used for a few days or more, the nasal spray needs prepared or "primed". Preparing the nasal spray help 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. 1) Hold the nasal spray upright, and put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle. 2) Point the nozzle away from you and keeping your thumb still, press down with your fingers to pump the spray. 3) Repeat this a few times until a fine mist of spray is released into the air. The nasal spray is now ready for use. <u>How to use the nasal spray</u> 1) Shake the nasal spray bottle. 2) Remove the dust cap. 3) Blow your nose gently to clear your nostrils, then tilt your head forward a little.
Patient or carer advice/follow up (continued)	4) 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. 5) 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. 6) 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 to treat the other nostril. 7) Wipe the nozzle carefully with a clean tissue and replace the dust cap. <u>Cleaning the nasal spray bottle</u> ➢ Clean your spray at least once a week, or more often if it gets blocked. Do not try to unblock the nasal applicator by inserting a

(continued over page)	pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine. 1) Take the dust cap off by gently squeezing the ribbed sides between your finger and thumb and lifting it off. Do not twist it off. 2) Pull upwards on the white collar to remove the nozzle. 3) Soak the nozzle and dust cap in warm water for a few minutes then rinse under a running tap. 4) Shake off the excess water and let them dry in a warm place. 5) Put the nozzle back on the spray. 6) 'Prime' the bottle as described in the section above "Preparing your nasal spray for use". <u>If more nasal spray than recommended is used</u> ➢ This is unlikely to cause any problems. Seek advice from your pharmacist if you are worried. ➢ If anyone, especially a child, accidentally drinks the nasal spray solution, contact your pharmacist, doctor or local hospital casualty department immediately. ➢ If you accidentally get nasal spray in your eyes, bathe them with plenty of water. They may sting for a while.

Patient or carer advice/follow up (continued)	<u>If a dose of the nasal spray is missed</u> ➢ Use the next dose when it is due. Do not use a double dose to make up for the forgotten dose. Inform the individual or their carer: **Lifestyle** ➢ Allergen avoidance (if a specific identified allergen is the cause of symptoms). Examples include: o wearing wraparound sunglasses to protect your eyes from pollen. o use hypoallergenic bedding and covers. Wash bedding regularly at ≥ 60°C. o dust with a damp cloth and use a vacuum with a HEPA filter. o do not allow pets in bedrooms and wash them at least once every 2 weeks and groom them outside regularly. o regularly wash your pet's bedding and clean any furniture they've been on. o avoid drying clothes outside when pollen count high. o keep your home dry and well-ventilated. Resolve any damp/condensation issues. ➢ Provision of information and support e.g. for hay fever, signposting to the Allergy UK website (https://www.allergyuk.org/types-of-allergies/hayfever/) **Signposting** Inform the individual or carer for both preparations: ➢ if they get any 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 if their condition deteriorates and/or

(continued over page)	they become systemically unwell. ➢ to read the PIL before taking the medication.
Patient or 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 their GP.
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, a record of the reason for exclusion and any specific advice that has been given must be documented within the consultation notes.

Appendices

Appendix A: *Key references*

- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 20 March 2023]
- Summary Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc/ [accessed 20 March 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: http://www.nice.org.uk/guidance/mpg2/resources [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: https://www.pharmacyregulation.org [accessed 20 March 2023]
- All Wales Medicines Strategy Group. All Wales Common Ailments Formulary. February 2018. Available from: https://awttc.nhs.wales [accessed 20 March 2023]
- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Allergic rhinitis. Last revised December 2022. Available from: https://cks.nice.org.uk [accessed 02 May 2023]
- Yellow Card Reporting. Available from: http://yellowcard.mhra.gov.uk [accessed 20 March 2023]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 20 March 2023]
- NHS Medicines A-Z. Available from: https://www.nhs.uk [accessed 20 March 2023]

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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
fluticasone propionate 50 micrograms/dose nasal spray by community pharmacists under the Clinical Community Pharmacy Service, Common Ailment 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