Patient Group Direction

For the supply of

Mometasone 50 micrograms/dose nasal spray

By 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

PGD for the supply of mometasone 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:	Mometasone 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
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...	9/15/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	9/18/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	9/19/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	25/08/2023

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 mometasone 50 micrograms/dose nasal spray. ➢ have awareness of the adverse drug reactions associated with mometasone 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 any training and competency assessments undertaken must be maintained.

4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of the symptoms of allergic rhinitis in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	Mometasone 50 micrograms/dose nasal spray can be supplied for: Individuals aged 3 years of age and over, presenting with symptoms of seasonal allergic or perennial rhinitis 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 mometasone 50 micrograms/dose nasal spray – see SmPC ➢ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion[2]	Mometasone 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) ➢ 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 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 nasal spray correctly for 4 weeks ➢ if allergy testing may be needed, e.g. if the individual has

[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.

Criteria for exclusion (continued)	➢ 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 cobicistat-containing products as this is expected to increase the risk of systemic side effects ➢ pregnancy ➢ breastfeeding ➢ to individuals with known hypersensitivity to mometasone 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)	Please refer to the SmPC for mometasone 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: ○ 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 affects are rare ➢ Individuals with cystic fibrosis should seek advice from a pharmacist or GP if they may be immunocompromised. ➢ 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

Cautions (including relevant actions to be taken)	➢ The nasal spray contains 20 micrograms benzalkonium chloride per actuation which may 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 mometasone 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	Mometasone furoate 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. Once symptoms are controlled, for maintenance, dose reduce to: ONE spray application in each nostril ONCE a day. **Children between the ages of 3 and 11 years** ONE spray application in each nostril ONCE a day.
Duration of treatment	This PGD only allows for the duration stated in the quantity to be supplied section below.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for TWO months. 1 x 140 dose pack to provide 2 months treatment at a dose of ONCE daily application (maintenance).

Drug interactions	➢ Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC. **Contraindication** ➢ Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. 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 mometasone.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects. 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 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 ➢ Pharyngitis ➢ Upper respiratory tract infection ➢ Headache ➢ Nasal burning ➢ Nasal irritation ➢ Nasal ulceration Not known (cannot be estimated from the available data) ➢ Glaucoma ➢ Increased intraocular pressure ➢ Cataracts, blurred vision ➢ Nasal septum perforation ➢ Taste and smell disturbances 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 seen for up to two days. **Directions for use** <u>Preparing your nasal spray for use</u> 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: 1) Gently shake the bottle. 2) Put your forefinger and middle finger on the collar either side of the nozzle and your thumb underneath the bottle. 3) 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. <u>How to use the nasal spray</u> 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. Repeat steps 4 to 5 for the other nostril. After using the spray, wipe the nozzle carefully with a clean tissue and replace the dust cap. <u>Cleaning the nasal spray bottle</u> If no spray appears and the nozzle may be blocked it needs cleaned. Cleaning the nasal spray at least once a week can prevent it from becoming blocked. 1) Remove the dust cap. 2) Gently pull upwards on the white collar to remove the nozzle.

Patient or carer advice/follow up (continued)	3) Soak the nozzle and dust cap in warm water for a few minutes, and then rinse under a running tap. 4) Allow to dry in a warm place before putting back together. Do not dry near a very hot place. 5) Re-fit the nozzle and 'prime' the bottle if necessary by pumping the spray a few times to produce a fine mist. Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine. <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. <u>If a dose of the nasal spray is missed</u> ➢ Use the spray as soon as you remember, then take the next dose at the usual time. ➢ Do not use a double dose to make up for a missed dose. **<u>Additional advice for individual or their carer</u>** **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

Patient or carer advice/follow up (continued)	➢ 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 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 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]

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
Mometasone 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