

Patient Group Direction

For the supply of

Fluticasone furoate 27.5 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 fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service

Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
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PGD for the supply of fluticasone furoate 27.5 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 furoate 27.5 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	20 th February 2023

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

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service

Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
 Valid From 01/07/2023
 Review Date 31/03/26
 Expiry Date 30/06/2026

1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group 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
Amy David	CPCAG reviewer	Primary Care Pharmacist, Swansea Bay UHB
Manjeet Singh	Medical Reviewer	Consultant in Acute Care, Aneurin Bevan UHB

Date CPCAG approval of PGD: 13th June 2023

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

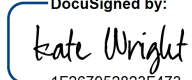
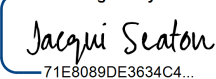


Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

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 Wrght	DocuSigned by:  1F267952823F473...	9/7/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by:  71E8089DE3634C4...	9/12/2023
Clinical Governance Lead for PTHB	Amanda Edwards	DocuSigned by:  74A4E51A42E9473...	9/12/2023
Senior Pharmacist Lead for Community Pharmacies PTHB	Emlyn Pritchard	DocuSigned by:  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.

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
 Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
 Valid From 01/07/2023
 Review Date 31/03/26
 Expiry Date 30/06/2026

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	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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 furoate 27.5 micrograms/dose nasal spray. ➤ have awareness of the adverse drug reactions associated with fluticasone furoate 27.5 micrograms/dose nasal spray. <p>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.</p>
Ongoing training and competency	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ 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.

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

	<ul style="list-style-type: none"> ➤ as registered professionals, be professionally accountable and must work within their competence. <p>A record of training and competence must be maintained in the individual's personal file.</p>
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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 Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	<p>Fluticasone furoate 27.5 micrograms/dose nasal spray can be supplied to individuals aged 6 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:</p> <ul style="list-style-type: none"> ➤ they have no contraindications to fluticasone furoate 27.5 micrograms/dose nasal spray – see SmPC ➤ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion²	<p>Fluticasone furoate 27.5 micrograms/dose nasal should not be supplied:</p> <p>Medical/symptom history</p> <ul style="list-style-type: none"> ➤ To individuals who present with red flag symptoms including: <ul style="list-style-type: none"> ○ fever ○ shortness of breath ○ recurrent epistaxis ○ 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.

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.

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

(continued over page)	<ul style="list-style-type: none">➤ 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.
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PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

<p>Criteria for exclusion (continued)</p>	<ul style="list-style-type: none"> ➤ 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. For example, if the individual has trialed 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 furoate 27.5 micrograms/dose nasal 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.
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PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

<p>Cautions (including relevant actions to be taken)</p>	<p>Please refer to the SmPC for fluticasone furoate 27.5 micrograms /dose nasal spray for full details of special warnings and precautions for use.</p> <ul style="list-style-type: none"> ➤ 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: <ul style="list-style-type: none"> ○ 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 ➤ 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 nasal spray contains benzalkonium chloride which may cause bronchospasm. It may also cause oedema of the nasal mucosa in long term use.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> ➤ 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 furoate 27.5 micrograms/dose nasal spray from the All Wales Common Ailments Service Formulary. Alternatively,

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service

Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

(continued over page)	refer the individual to their GP if appropriate and/or provide them with information about further options.
Action to be taken if the individual is excluded or declines treatment (continued)	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 furoate 27.5 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	<p>Adults and children aged 12 years and over:</p> <p>Initially: TWO spray applications in each nostril ONCE a day.</p> <p>Once symptoms are controlled, for maintenance, dose reduce to: ONE spray application in each nostril ONCE a day.</p> <p>Children between the ages of 6 and 11 years:</p> <p>The recommended starting dose is: ONE spray application in each nostril ONCE a day.</p> <p>If an adequate response at this dose is not achieved within 3-7 days, the following dose can be trialled: TWO spray applications in each nostril ONCE a day.</p>

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

	Once adequate control of symptoms is achieved, dose reduction to ONE spray application in each nostril ONCE daily is recommended.
Duration of treatment	This PGD only allows for the duration stated in the dosage schedule above.
Quantity to be supplied/administered	Appropriately labelled pack to provide treatment for TWO months. 1 x 120 dose pack to provide 2 months treatment at a dose of ONCE daily application.
Drug interactions (continued over page)	<ul style="list-style-type: none"> ➤ Interactions do not generally apply to corticosteroids used for intranasal action unless specified in the BNF or SmPC. ➤ 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
Drug interactions (continued)	<p>risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.</p> <p>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.</p>
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects.</p> <p>If the patient experiences any of the following they must discontinue treatment:</p> <ul style="list-style-type: none"> ➤ 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 <p>The following side effects have been reported as:</p> <p><u>Very common to common</u> (affecting less than 1 in 10 or between 1 in 10 and 1 in 100 patients)</p> <ul style="list-style-type: none"> ➤ Headache

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

(continued over page)	<ul style="list-style-type: none"> ➤ Nasal ulceration ➤ Dyspnoea ➤ Epistaxis <p><u>Uncommon</u> (affecting between 1 in 100 and 1 in 1000 patients)</p> <ul style="list-style-type: none"> ➤ Rhinalgia ➤ Nasal discomfort (including nasal burning, nasal irritation and nasal soreness) ➤ Nasal dryness <p><u>Very rare</u> (affecting less than in 1 in 10000 patients)</p> <ul style="list-style-type: none"> ➤ Nasal septum perforation <p><u>Not known</u> (cannot be estimated from the available data)</p> <ul style="list-style-type: none"> ➤ Transient ocular changes including blurred vision
Identification & management of adverse reactions (continued)	<ul style="list-style-type: none"> ➤ Bronchospasm ➤ Growth retardation <p>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.</p>

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

<p>Patient or carer advice/follow up</p> <p>(continued over page)</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>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 2 weeks.</p> <p>Directions for use</p> <p><u>Preparing your nasal spray for use</u></p> <p>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 prepared. Preparing the nasal spray help to make sure you always get the full dose of medicine.</p> <ol style="list-style-type: none"> 1) 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. 2) Remove the cap by squeezing firmly on the sides of the cap with your thumb and forefinger. 3) Hold the nasal spray upright, then tilt and point the nozzle away from you. 4) 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. <p><u>How to use the nasal spray</u></p> <p>Correct technique is very important when using nasal sprays to give the best chance of a satisfactory response to the medication.</p> <ol style="list-style-type: none"> 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.
<p>Patient or carer advice/follow up</p> <p>(continued)</p>	<ol style="list-style-type: none"> 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

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

(continued over page)	<p>time press down firmly on the button of the bottle. This will release a spray of fluticasone furoate.</p> <p>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.</p> <p>7) Replace the cap on the nasal spray.</p> <p><u>Cleaning the nasal spray bottle</u></p> <ul style="list-style-type: none"> ➤ After each use wipe the nozzle and inside of the cap with a clean, dry tissue. Do not use water to clean it. Always replace the cap once you have finished. ➤ If no spray appears and the nozzle may be blocked it needs cleaned. ➤ 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. <p><u>If more nasal spray than recommended is used</u></p> <ul style="list-style-type: none"> ➤ 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. <p><u>If a dose of the nasal spray is missed</u></p> <ul style="list-style-type: none"> ➤ Use the spray as soon as you remember, then take the next dose at the usual time. ➤ If it is nearly time for your next dose, wait until then. Do not use a double dose to make up for a missed dose.
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Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

<p>Patient or carer advice/follow up (continued)</p>	<p>Lifestyle</p> <ul style="list-style-type: none"> ➤ Allergen avoidance (if a specific identified allergen is the cause of symptoms). Examples include: <ul style="list-style-type: none"> ○ wearing wraparound sunglasses to protect your eyes from pollen. ○ use hypoallergenic bedding and covers; wash bedding regularly at $\geq 60^{\circ}\text{C}$. ○ dust with a damp cloth and use a vacuum with a HEPA filter. ○ do not allow pets in bedrooms and wash them at least once every 2 weeks and groom them outside regularly. ○ regularly wash your pet's bedding and clean any furniture they've been on. ○ avoid drying clothes outside when pollen count high. ○ 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/) <p>Signposting</p> <p>Inform the individual or carer for both preparations:</p> <ul style="list-style-type: none"> ➤ 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 they become systemically unwell. ➤ to read the PIL before taking the medication. ➤ to visit the NHS website on allergic rhinitis for more information. <p>If fever, shortness of breath, recurrent epistaxis or nasal pain occurs, the individual should seek review with their GP.</p>
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PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

Records	<p>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.</p> <p>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.</p>
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PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

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]

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of:
fluticasone furoate 27.5 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

PGD for the supply of fluticasone furoate 27.5 micrograms/dose nasal spray for the treatment of symptoms of allergic rhinitis as part of the Community Pharmacy Common Ailment Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026

Reg No: PGD 0221
Valid From 01/07/2023
Review Date 31/03/26
Expiry Date 30/06/2026