

Patient Information Leaflet
Decongestant 0.05% w/v
Nasal Spray
(Oxymetazoline Hydrochloride)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Decongestant Nasal Spray is and what it is used for
2. What you need to know before you use Decongestant Nasal Spray
3. How to use Decongestant Nasal Spray
4. Possible side effects
5. How to store Decongestant Nasal Spray
6. Contents of the pack and other information

1. What Decongestant Nasal Spray is and what it is used for
 This nasal spray contains Oxymetazoline Hydrochloride which is a decongestant. It relieves a stuffy, blocked nose by shrinking the blood vessels helping to open the nasal passages. It acts within a few minutes and lasts for up to 12 hours.

The medicine is a solution which is sprayed into the nostrils to relieve the congestion in the nose and sinuses which you get in conditions such as colds, catarrh and hayfever.

2. What you need to know before you use Decongestant Nasal Spray

Do not use this nasal spray if you:

- are allergic to oxymetazoline or any of the other ingredients of this medicine (listed in section 6)

- have pheochromocytoma (a rare benign tumour of the adrenal glands that produces high amounts of adrenaline and noradrenaline)
- have had an operation to remove your pituitary gland or you have recently had an operation on your nose or sinuses
- are already taking medicines to unblock your nose
- have inflamed skin or mucous membranes of your nostrils or have scabs in your nose
- have chronic nasal inflammation with very dry nasal passageways (atrophic rhinitis or rhinitis sicca).

Do not give this nasal spray to children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using this nasal spray, if you:

- have an enlarged prostate or other prostate problems (as there is a risk for development of difficulty passing urine)
- are elderly
- have damage to the nerve in the eye caused by pressure inside the eye rising rapidly because fluid cannot drain out (angle closure glaucoma)
- have coronary heart disease, or any other heart condition (e.g. angina)
- have high blood pressure
- have an over-active thyroid gland (hyperthyroidism) or other problems with your thyroid function
- have diabetes
- have kidney or liver problems
- are taking medicines for depression (tricyclic antidepressants (e.g. amitriptyline, imipramine) or monoamine oxidase inhibitors) or used such treatments during the last two weeks.

If any of the following occur, this nasal spray should be stopped:

- hallucinations
- restlessness
- sleep disturbances.

Keep away from the eyes.

Other medicines and Decongestant Nasal Spray

- Tell your doctor or pharmacist if you are taking or using, or have recently taken or used any other medicines, especially:
 - Monoamine Oxidase Inhibitors (used for treatment of depression). If you are taking or have taken these medicines in the last two weeks, your blood pressure may increase significantly
 - Beta-blockers (for treatment of high blood pressure). Do not use if you are taking beta blockers as their effect may be reduced

- Other decongestant products. Do not use if you are taking other decongestant products, e.g. ephedrine and pseudoephedrine
 - Tricyclic antidepressants (drugs used in the treatment of depression such as amitriptyline and imipramine)
 - High blood pressure medicines (such as bethanidine, debrisoquine and guanethidine) as their effect may be reduced
 - Parkinson's disease medicine (bromocriptine and rasagiline) treatment may be affected if it is used at the same time
 - Digoxin or digitoxin for heart failure, as it can cause irregular heartbeat (dysrhythmias) if it is taken at the same time
 - Ergotamine or methysergide for migraine relief
 - Medicines or supplements to reduce appetite or make you more alert (amphetamine-like psychostimulants) as these can give rise to additive effects
 - Thyroid hormones e.g., levothyroxine
 - Oxytocin used to assist birth or breastfeeding.
- If you are taking any other medicines, you should see your doctor or pharmacist for advice before using this medicine.

Pregnancy and breastfeeding

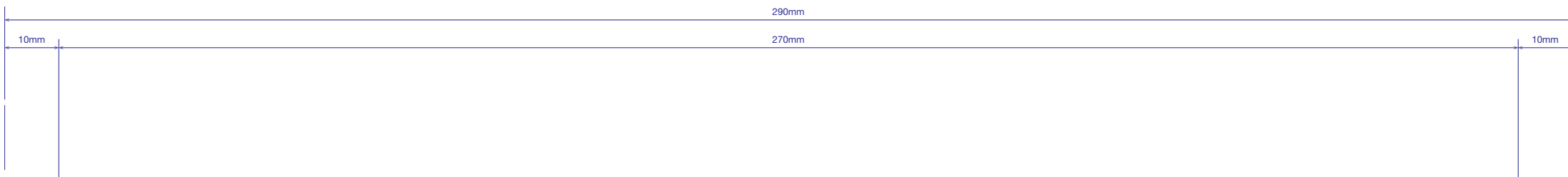
Do not use if you are pregnant. Talk to your doctor or pharmacist before using the nasal spray if you are breastfeeding, think you may be pregnant or are planning to have a baby before taking this medicine.

Driving and using machines

No effect on ability to drive or use of machinery has been observed.

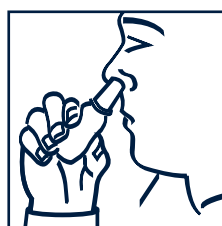
Important information about some of the ingredients of this medicine:

- This medicine contains 0.4 mg benzalkonium chloride in each 1 ml which is equivalent to 6 mg/15ml and 8mg/20ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.
 - Benzalkonium chloride can also cause shortness of breath.
 - Contains thiomersal as a preservative which may cause local skin reactions (e.g. contact dermatitis) and discolouration. It may also cause allergic reactions.
- Tell your doctor if you have any known allergies.



3. How to use Decongestant Nasal Spray

For nasal use only



Age	Dose and how to use	How often to use
Adults, the elderly and children aged 12 years and above	See diagram Remove the cap. Hold the container upright, place the tip of the spray nozzle just into each nostril. Hold the other nostril closed. Lightly squeeze the container twice as you breathe in through the nose at the same time. Repeat for the other nostril. Wipe the nasal applicator with a clean, wet tissue and replace the cap immediately after application.	The nasal spray dose may be applied up to twice daily, or used at bedtime to give relief through the night.

Do not use in children under 12 years

Do not exceed the stated dose.
Do not use continuously for more than 7 days.
 This product is not suitable for long-term use (see also section 4 'Possible Side Effects').
 If symptoms persist, consult your doctor.

If you do not understand these instructions or if you require any further information about your medicine, ask your doctor or pharmacist.

If you use more Decongestant Nasal Spray than you should:

If you have used more spray than the stated dose, talk to a doctor or pharmacist immediately.

- 4. Possible side effects**
 Most people use this nasal spray without any problems but, like all medicines, it can have side effects.

Allergic reaction

Stop using the nasal spray and contact your doctor or go to your nearest hospital casualty department immediately if you notice:

- skin rashes or itching
- sneezing or stinging or burning of the nose
- swelling of the nose, lips, tongue or throat
- shortness of breath or difficulty in breathing.

Other side effects

- Rare: Eye irritation, dryness, discomfort or redness
- Very Rare: Nervousness
- Not Known:
 - ✓ Irritation, dryness or soreness in the nose, mouth or throat
 - ✓ Headache, Dizziness
 - ✓ Weakness, Fatigue and trembling
 - ✓ Anxiety, Fear, Irritability, Restlessness or sleep disturbance, Confusion or seeing things (psychotic disorder)
 - ✓ Tremor
 - ✓ Pain
 - ✓ Nausea (feeling sick), vomiting (being sick), less saliva than usual in your mouth, decreased appetite
 - ✓ Flushing and visual disturbances
 - ✓ Effects on the heart e.g. abnormal rapid or irregular heartbeat, an increase in awareness of your heartbeat (palpitations)
 - ✓ Effects on the circulation e.g. cold feet or hands, high blood pressure
 - ✓ If the spray is used regularly over a long period, it may cause a condition called rebound congestion. This is a drug induced stuffy and runny nose with unusual swelling of the lining of the nose, leading to itching, sneezing and a blocked nose following the last dose of the spray. Therefore, do not use the spray continuously for more than 7 days
 - ✓ This product contains thiomersal as a preservative and it is possible that this may cause local skin reactions (e.g., contact dermatitis) and skin discolouration around the nose. It may also cause an allergic reaction (see above)
 - ✓ Prolonged and/or heavy use beyond the recommended use of 7 days, may lead to cardiovascular and/or CNS effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Decongestant Nasal Spray

Do not use this medicine after the expiry date shown on the bottle and the carton.

Keep out of the sight and reach of children.

6. Contents of the pack and other information

What is in this nasal spray?

The active ingredient is: Oxymetazoline hydrochloride 0.05% w/v.
Other ingredients are: Benzalkonium chloride, thiomersal, sodium chloride, menthol, eucalyptol, camphor, methyl salicylate, poloxamer, sodium citrate, anhydrous citric acid and purified water.

What this medicine looks like and the contents of the pack
 The product is a clear liquid which is sprayed in fine droplets out of the nozzle of the container. A pack contains a white 15 ml bottle.

Marketing Authorisation Holder:
 Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufactured for The Boots Company PLC, Nottingham, NG2 3AA by the **Manufacturer:** Omega Pharma Ltd, DMC 02, County Way, Barnsley, South Yorkshire, S70 2AG, United Kingdom.

Text revised: October 2024

Other formats

To request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)
 Please be ready to give the following information:
 Product name: Boots Decongestant 0.05% w/v Nasal Spray
 Reference number: PL 16028/0049
 This is a service provided by the Royal National Institute of Blind People.

B8S89QA:J6

