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Direction of travel past pharmacode scanner
First bar
80mm Lead-in
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Galpharm Blocked Nose Relief 0.05% w/v Nasal Spray

(Oxymetazoline Hydrochloride 0.05% w/v)

PATIENT INFORMATION LEAFLET

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

1 WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR

This medicine 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 THIS MEDICINE

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 phaeochromocytoma (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)
- 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
- Are taking monoamine oxidase inhibitors for depression or used such treatments during the last two weeks
- Are under 12 years of age.

Warnings and precautions
Talk to your doctor before using this medicine, if you:
- Have an enlarged prostate or other prostate problems (as there is a risk for development of difficulty passing urine)
- Have occlusive vascular disease (narrowed blood vessels)
- Are elderly
- Have kidney or liver problems
- Are taking tricyclic antidepressants for depression (e.g. amitriptyline, imipramine).

If symptoms persist or do not improve after 7 days, a doctor should be consulted.

Do not use this medicinal product for more than 7 consecutive days to avoid drug induced stuffy and runny nose (rebound effect and drug induced rhinitis (rhinitis medicamentosa)).

If any of the following occur, this medicine should be stopped:
- hallucinations
- restlessness
- sleep disturbances.

Keep away from eyes.

Children
Do not give this medicine to children under 12 years of age.

Other medicines and this medicine
Tell your doctor or pharmacist if you are taking or using, or have recently taken or used any other medicines, especially:
- Monoamine Oxidase Inhibitors and/or Reversible Inhibitors of Monoamine Oxidase A (used for treatment of depression, e.g. moclobemide, rasagiline). If you are taking or have taken these medicines in the last two weeks, your blood pressure may increase significantly
- Beta-blockers or adrenergic neurone 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 taking this medicine.

Pregnancy, breastfeeding and fertility
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 0.4mg benzalkonium chloride in each 1ml which is equivalent to 6mg/15ml and 8mg/20ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Further information overleaf ➥

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- 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 THIS MEDICINE

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 daily dose or the specified number of doses. **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 of this medicine than you should:
If you have used more spray than the stated dose, talk to a doctor or pharmacist immediately.

4 POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reaction
Stop using the nasal spray and contact your doctor or go to the 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, swelling or soreness in the nose, mouth or throat
✓ Swelling of the lips, tongue
✓ Headache, Dizziness
✓ Weakness, fatigue
✓ Anxiety, Fear, Irritability, Restlessness or sleep disturbance, Confusion or seeing things (psychotic disorder)
✓ Sleep disorder in children
✓ Tremor
✓ Sleepiness
✓ Sneezing
✓ 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
✓ Drug tolerance with drug effect decreased
✓ 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 THIS MEDICINE

Do not use this medicine after the expiry date shown on the bottle and carton. The expiry date refers to the last day of that month.
Keep this medicine out of the sight and reach of children.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What is in this medicine?
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 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 15ml bottle.

Marketing Authorisation Holder and Manufacturer:

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

Manufacturer: Omega Pharma Ltd, DMC 02, County Way, Barnsley, South Yorkshire, S70 2AG, United Kingdom.

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MINIMUM TYPE SIZE **8pt**