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

# WHAT NUMARK NASAL DECONGESTANT SPRAY IS AND WHAT IT IS USED FOR

Numark Nasal Decongestant Spray contains Oxymetazoline Hydrochloride which is a decongestant. It relieves a stuffy, blocked nose by shrinking the blood vessels helping to open the pasal 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 NUMARK NASAL DECONGESTANT 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 phaeochromocytoma (a rare tumour of the adrenal glands)
- 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 vour nose
- Have inflamed skin or mucous membranes of your nostrils or have scabs in your nose.

Do not give Numark Nasal Decongestant Spray to children under 12 years of age.

#### Warnings and precautions

#### Talk to your doctor or pharmacist before using Numark Nasal Decongestant Spray, if you:

- Have prostate problems
- Are elderly
- Have glaucoma (increased pressure in the eye)
- Have coronary heart disease, cardiac asthma, or any other heart condition
- Have high blood pressure
- · Have an over-active thyroid gland or other problems with your thyroid function
- Have diabetes
- Have kidney or liver problems.

#### If any of the following occur, Numark Nasal Decongestant Spray should be stopped;

- hallucinations
- sleep disturbances.

### Keep away from eyes.

#### Other medicines and Numark Nasal **Decongestant Spray**

Tell your doctor or pharmacist if you are taking or using, or have recently taken or used any other

- Do not use if you are taking or have recently taken Monoamine Oxidase Inhibitors (see above)
- Do not use if you are taking beta blockers as their effect may be reduced
- 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 (bromcriptine) 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 heart beat (dysrhthmias) 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)
- 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 and breastfeeding
Do not use if you are pregnant. Talk to your doctor or pharmacist before using the nasal spray if you are breastfeeding.

### **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:

- Contains benzalkonium chloride which is an irritant and may cause skin reactions
- 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.

Further information overleaf

# HOW TO USE NUMARK NASAL DECONGESTANT 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 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 too much:

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 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

- Irritation, dryness or soreness in the nose mouth or throat
- Eye irritation, dryness, discomfort or redness

- Headache, dizziness
- Weakness, fatigue and trembling
- Anxiety, fear, irritability, nervousness, restless or not sleeping, confused or seeing things
- 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. rapid or irregular 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 an 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 discolouration around the nose. It may also cause an allergic reaction
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

# HOW TO STORE NUMARK NASAL DECONGESTANT SPRAY

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

### Manufacturer:

Galpharm International Ltd., Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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