

## Package leaflet: Information for the user

### **Sudafed Blocked Nose 1mg/ml Nasal Spray Solution** *xylometazoline hydrochloride*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

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

#### **1. What Sudafed Blocked Nose Nasal Spray is and what it is used for**

Olynth HA 1mg/ml contains Xylometazoline, which helps to narrow the blood vessels in your nose, reducing swelling of the mucous membrane (the lining in your nose), to help you breathe easier. Sudafed Blocked Nose Nasal Spray also contains hyaluronic acid (in the form of sodium hyaluronate), which protects and moisturises the mucous membrane of the nose.

The spray is used for short term treatment of nasal congestion with a running nose due to common cold or sinusitis.

#### **2. What you need to know before you use Sudafed Blocked Nose Nasal Spray**

**Do not use Sudafed Blocked Nose Nasal Spray if you:**

- are allergic to xylometazoline or any of the other ingredients of this medicine (listed in Section 6)
- have increased pressure in your eye, especially if you have narrow angle glaucoma
- have chronic rhinitis (long term nasal inflammation) with little or no secretion (*rhinitis sicca*)
- are being treated with monoamine oxidase inhibitors (MAOIs) or if you have used MAOIs in the last 2 weeks
- are being treated with other medicines that could raise your blood pressure
- have inflammation caused by the blood vessels in your nose being over-sensitive
- have inflammation associated with thinning of the nasal membranes with or without discharge
- have had recent brain surgery via the nose or mouth

This spray is NOT for use in children under 12 years of age.

## **Warnings and precautions**

Talk to your doctor or pharmacist **before** using the spray if you:

- react strongly to sympathomimetics (adrenaline-like products) as the use of Sudafed Blocked Nose Nasal Spray may cause sleeplessness, dizziness, uncontrollable trembling or shaking movements, irregular heartbeat or abnormal heart rhythm, or an increase in blood pressure
- have a heart problem, blood vessel problem or high blood pressure
- have an overactive thyroid, diabetes or any other metabolic disorders
- have a disease of your adrenal glands
- have an enlarged prostate gland (prostatic hypertrophy).

**Continuous use of the product over long periods** can result in worsening of congestion symptoms.

## **Other medicines and Sudafed Blocked Nose Nasal Spray**

Talk to your doctor or pharmacist before using Sudafed Blocked Nose Nasal Spray.

Do NOT use the spray if you are taking:

- certain antidepressants, such as tri- or tetracyclic antidepressants or MAOIs or if you have taken MAOIs in the last 2 weeks (see section 'Do not use')
- other medicines that could raise your blood pressure.

Please tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

## **Pregnancy and breast-feeding**

If you are pregnant or think you might be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Sudafed Blocked Nose Nasal Spray should not be used during pregnancy as little is known about its action on the unborn child.

If you are breast-feeding discuss with your doctor before using this product. It is not known whether the active substance is transferred into breast milk.

## **Driving and using machines**

SUDAFED BLOCKED NOSE NASAL SPRAY has no known effect on the ability to drive and use machines.

## **3. How to use Sudafed Blocked Nose Nasal Spray**

### **Adults and children aged from 12 years.**

Unless otherwise directed by a doctor or pharmacist, use one spray of Sudafed Blocked Nose Nasal Spray in each nostril up to 3 times a day **for a maximum of 7 days**.

1. Take off the protective cap. Prime the bottle before using by pushing several times until the spray comes out in a steady squirt (see Figure 1). The spray is now ready to use.
2. Hold the bottle upright. Insert the nozzle into your nostril - do not spray from below the nostril (see Figure 2).
3. Press the pump once. At the time of vaporization breathe in through the nose. Repeat for the other nostril.
4. After use, put the protection cap back on the bottle.



To reduce the risk of spreading infections, the bottle should not be used by more than one person, and the nozzle should be rinsed after each use.

Do NOT use this spray in children under 12 years.

#### **If you use more Sudafed Blocked Nose Nasal Spray than you should**

Contact your doctor, pharmacist or nearest hospital casualty department immediately, and take the medicine or this leaflet with you.

#### **If you forget to use Sudafed Blocked Nose Nasal Spray**

If you forget to take a dose, take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, Sudafed Blocked Nose Nasal Spray can cause side effects, although not everybody gets them.

**STOP using the spray and seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

#### **Other side effects may include:**

**Common** (may affect up to 1 in 10 people):

- stinging or burning sensation in the nose and throat and dry lining of the nose (nasal mucosa).

**Rare** (may affect up to 1 in 1,000 people):

- headache, raised blood pressure, nervousness, feeling sick, dizziness, sleeplessness and heart palpitations
- temporary visual disturbances and systemic allergic reactions.

**Not known** (frequency cannot be estimated from the available data):

- worsening of congestion symptoms after stopping use of the product.
- nose bleeding

#### **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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517 Website: [www.hpra.ie](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## **5. How to store Sudafed Blocked Nose Nasal Spray**

Keep out of the sight and reach of children.

Do not store above 25°C.

After opening, do NOT use Sudafed Blocked Nose Nasal Spray for more than 12 months.

Do not use Sudafed Blocked Nose Nasal Spray after the expiry date which is stated on the carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that are no longer in use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Sudafed Blocked Nose Nasal Spray contains**

The **active substance** is xylometazoline hydrochloride, of which there is 1 mg per millilitre of solution. Each actuation of Sudafed Blocked Nose Nasal Spray (= 140 µl) contains 140 µg of xylometazoline hydrochloride.

The **other ingredients** are sodium hyaluronate, sorbitol (E420), glycerol (E422), sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium chloride and water for injections.

### **What Olynth HA looks like and contents of the pack**

The spray is clear to slightly opalescent, colourless to slightly yellowish solution in a white plastic 10 ml bottle with a dosage pump.

### **Marketing Authorisation Holder**

McNeil Healthcare (Ireland) Limited  
Airton Road  
Tallaght  
Dublin 24  
Ireland

### **Manufacturer**

Ursapharm Arzneimittel GmbH  
Industriestrasse  
66129 Saarbrücken  
Germany  
or

FAMAR HEALTH CARE SERVICES MADRID, S.A.U.  
Avda. Leganés, 62  
Alcorcón  
28923 Madrid  
Spain

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Latvia: Sudafed Blocked Nose Nasal Spray deguna aerosols bez konservantiem, šķīdums  
Cyprus: Hexarhinal

Denmark:	Olynth
Greece:	Hexarhinal
Finland:	Bafunasal 1 mg/ml nenäsumute, liuos
Ireland:	Sudafed Blocked Nose 1mg/ml Nasal Spray Solution
Iceland:	Olynth
Italy:	ACTIGRIP NASALE “1mg/ml spray nasale, soluzione” 1 flacone da 10 ml
Norway:	Olynth 1 mg/ml neseppray, oppløsning
Portugal:	Nasexilo 1 mg/ml solução para pulverização nasal, sem conservantes
Romania:	Sudafed Blocked Nose Nasal Spray spray nazal, solutie
Sweden:	Olynth

**This leaflet was last revised on October 2015**