

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sudafed Blocked Nose 1 mg/ml Nasal Spray Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Xylometazoline hydrochloride 1 mg in 1 ml of solution

Each actuation (140µl) contains 140µg of xylometazoline hydrochloride

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray, solution.

Clear to slightly opalescent, colourless to slightly yellowish solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Temporary symptomatic treatment of nasal congestion due to rhinitis or sinusitis.

4.2 Posology and method of administration

For nasal use.

Adults and children over 12 years old:

One spray, into each nostril not more often than three times per day. This medicine should be used for a maximum of 7 days, unless directed otherwise by a doctor.

To minimise the risk of spreading infections, the medicinal product should not be used by more than one person, and the nozzle should be rinsed following use.

Paediatric population

Sudafed Blocked Nose Nasal Spray Solution, 1 mg/ml is contraindicated in children less than 12 years of age (See section 4.3).

Elderly patients

Dosage as for adults.

4.3 Contraindications

Sudafed Blocked Nose Nasal Spray Solution 1mg/ml should not be used:

- in patients with hypersensitivity to the active substance or to any of the excipients stated in Section 6.1.
- in patients with increased intraocular pressure, particularly in patients with narrow angle glaucoma
- in patients with dry inflammation of the nasal mucus membrane (*Rhinitis sicca*)
- in children under 12 years of age
- after transsphenoidal hypophysectomy or such transnasal / transoral operations where the dura mater has been exposed
- in patients who are being treated with monoaminooxidase inhibitors (MAOI) or those who have used them within the previous 2 weeks, or other medicaments with potential hypertensive effect

- in patients who have atrophic or vasomotor rhinitis

4.4 Special warnings and precautions for use

Xylometazoline as well as other medicinal products of the same group should be administered with caution to patients who react strongly to sympathomimetics. Using these may cause them to suffer from, for example, insomnia, vertigo, tremor, arrhythmia or a rise in blood pressure.

Care should be taken in the treatment of patients who suffer from cardiac or vascular diseases, hypertension, hyperthyroidism or diabetes, as well as in conjunction with hypertrophy of the prostate and with phaeochromocytoma.

If xylometazoline treatment is continued long-term, the symptoms of rhinitis and the swelling of the mucous membrane may sometimes recur on discontinuation. In such instances this may also be due to the so-called rebound phenomenon caused by the medication itself, which can progress to chronic swelling and atrophy of the nasal mucous membrane (*Rhinitis medicamentosa & Rhinitis sicca*). In order to avoid this, the duration of treatment should be restricted to the shortest possible period (see 4.2). Any nasal and paranasal bacterial inflammations should be treated appropriately. For the treatment of allergic rhinitis, this product may only be used as a temporary support treatment.

4.5 Interaction with other medicinal products and other forms of interaction

The use of xylometazoline concomitantly with tri- or tetracyclic antidepressants or monoamine oxidase (MAO) blockers, or for two weeks after the use of MAO blockers, is not recommended.

4.6 Fertility, pregnancy and lactation

No information is available on the conveyance of xylometazoline through the placenta or on its secretion into mother's milk. Owing to its potential systemic effect of vascular constriction, this product should not be used during pregnancy. During lactation this product should be used with caution as it is not known whether the active substance is transferred into breast milk.

4.7 Effects on ability to drive and use machines

When used correctly, xylometazoline is not known to have any influence on the ability to drive and use machines.

4.8 Undesirable effects

The most frequently reported undesirable effects of this medicinal product have been smarting or burning of nose and throat, and drying of the mucous membrane of the nose.

The frequency categories of the undesirable effects have been defined as follows: Common

Very common	≥1/10
Common	≥1/100 to <1/10
Uncommon	≥1/1,000 to <1/100
Rare	≥1/10,000 to <1/1,000
Very rare	<1/10,000 including isolated reports
Not known	cannot be estimated from available data

	Common	Rare	Not known
Immune system disorders		Systemic allergic reactions	
Psychiatric disorders		Nervousness, insomnia	
Nervous system		Headache, dizziness	

disorders			
Eyes disorders		Transient optical disorders	
Cardiac disorders		Palpitation	
Vascular disorders		Rise in blood pressure	
Respiratory, thorax and mediastinal disorders	Smarting or burning of nose and throat, and drying of the mucous membrane of the nose		Rebound effect Epistaxis
Gastrointestinal disorders		Nausea	

4.9 Overdose

As an imidazoline, systemic overdose of xylometazoline may result in a wide range of symptoms referable to cardiac and nervous system stimulation or depression.

Cases of overdosing have been described as mainly occurring in conjunction with children. The poisoning symptoms reported have included serious paralysis of the central nervous system, sedation, dryness of mouth and perspiration, as well as symptoms caused by the stimulation of the sympathetic nervous system (tachycardia, irregular pulse and rise in blood pressure). A drop (single dose) of the xylometazoline preparation intended for adults (1 mg/ml) administered intranasally caused a four-hour coma in a 15-day-old infant. During the follow-up, the infant recovered fully.

Treatment of poisoning is nosotropic, and may include administration of charcoal, gastric lavage & oxygen inhalation. For reducing blood pressure 5mg of phentolamine is administered slowly by iv in saline solution or 100mg orally. If required, antipyretics and anticonvulsants are administered. Vasopressors are contraindicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics, ATC code: R01AA07.

Xylometazoline is an imidazole derivative with a sympathomimetic effect. Xylometazoline sprayed onto nasal mucous membrane quickly causes a long-lasting vascular constriction, as a result of which the blocking of the nose is reduced.

This effect may be conveyed through the direct stimulation of the postsynaptic alpha receptors. Xylometazoline is not known to have any effect on adrenergic beta receptors.

In the treatment of allergic rhinitis, xylometazoline sprayed into the nose is only suitable for temporary use or for facilitating the administration of another medicinal product that has a topical effect on the nasal mucous membrane.

The rebound symptoms (swelling of the mucous membrane and blocking) that sometimes occur as a result of long-term use may be caused by the medicinal product's effect of stimulating the presynaptic alpha2-receptors and reducing the release of noradrenalin. With vasoconstrictors the rebound symptoms usually appear after 2-3 weeks of continuous treatment, but xylometazoline has been administered to healthy test subjects even for 6 weeks without any swelling of mucous membranes or tachyphylaxis occurring in them.

In vitro, xylometazoline has been found to impair the functioning of kinocilia, but this effect is not permanent.

Sudafed Blocked Nose Nasal Spray Solution, 1 mg/ml contains, among others, hyaluronic acid (in the form of sodium hyaluronate), which provides the moisturizing effect on the mucous membrane of the nose.

5.2 Pharmacokinetic properties

In topical use, vasoconstriction is normally achieved within 5-10 minutes after administering the medicinal product. The effect of reducing the blocking of the nose usually lasts for approx. 6-8 hours. When used and dosed correctly, the absorption of the medicinal product into systemic circulation is very negligible. However, with large doses and when ingested, absorption and consequential systemic effects may occur. There is scarcely any information available on the distribution, metabolism or secretion of xylometazoline in the human organ system.

5.3 Preclinical safety data

No essential data with regard to clinical safety.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hyaluronate
Sorbitol (E420)
Glycerol (E422)
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

Sudafed Blocked Nose Nasal Spray Solution, 1 mg/ml should not be used longer than 12 months after opening. Do not use after the expiry date which is stated on the pack.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White HDPE bottle containing 10 ml nasal spray solution with a 3K pump system, plastic cover, carton box.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0823/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 2011

Date of last renewal: 20th October 2015

10 DATE OF REVISION OF THE TEXT

January 2016