

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sudafed Plus Blocked Nose 1mg/50mg/ml Nasal Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of nasal spray, solution, contains 1 mg xylometazoline hydrochloride and 50 mg dexpanthenol.

One spray contains 0.1 ml of nasal spray, solution, containing 0.1 mg xylometazoline hydrochloride and 5.0 mg dexpanthenol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

Clear, colourless to slightly yellowish solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is indicated for adults and children 12 years and older:

- For the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies (see section 5.1).

4.2 Posology and method of administration

Posology

Adults and children 12 years and over:

One spray into each nostril up to 3 times a day, as necessary.

Maximum daily dose: 3 sprays in 24 hours.

The dosage depends on individual sensitivity and clinical efficacy.

Use for more than seven consecutive days is not recommended (See section 4.4). Do not exceed the recommended dose.

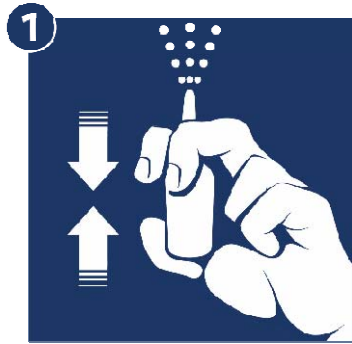
Children under 12 years:

Do not give to children under 12 years of age.

For hygienic reasons and to avoid infections, each spray bottle should only be used by the same person.

Method of administration: Nasal

First the protective cap should be removed from the sprayer.
Before the first use the spray head should be pressed five times away from the face until a fine spray appears. If the spray has not been used for a long period of time the head should be pressed two times away from the face before use.



The sprayer tip should be inserted as upright as possible into one nostril and the spray head should be pressed once. Patient should gently inhale through the nose while spraying. If necessary, the procedure should be repeated for the other nostril.



After each use, the sprayer tip should be wiped with a paper tissue and the cap placed back on the sprayer.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Contraindicated in children under 12 years of age.

Concomitant use of other sympathomimetic decongestants.

Cardiovascular disease including hypertension.

Phaeochromocytoma.

Diabetes Mellitus

Hyperthyroidism

Closed angle glaucoma.

Contraindicated in individuals who are taking beta blockers (see section 4.5).

Inflammation of the skin and/or mucosa of the nasal vestibule.

Contraindicated in individuals with dry inflammation of the nasal mucosa (rhinitis sicca).

Contraindicated in individuals who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks (see section 4.5).

Contraindicated in individuals with a history of transsphenoidal hypophysectomy or other surgical interventions which expose the dura mater.

4.4 Special warnings and precautions for use

There is minimal systemic absorption with topically applied imidazoline sympathomimetics such as xylometazoline.

This medicinal product may be used only after a careful assessment of the risks and benefits in cases of:

- increased intraocular pressure
- porphyria
- prostate hyperplasia.

Use during chronic rhinitis may only be carried out under medical supervision owing to the danger of the atrophy of the nasal mucosa.

Use with caution in occlusive vascular disease.

Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.

This medicine is intended for short term use only. Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. This rebound effect may lead to nasal congestion or nasal obstruction during continued use or after discontinuation, resulting in repeated or even continuous use of the medicine by the patient (See section 4.8).

Keep away from the eyes.

In case of misuse or use of excessive amounts of the spray, the absorption of xylometazoline can cause systemic adverse effects (cardiovascular and neurological adverse effects) (see sections 4.8 and 4.9).

If any of the following occur, use of Sudafed Plus Blocked Nose Spray should be stopped:

- Hallucinations
- Restlessness
- Sleep disturbances

4.5 Interaction with other medicinal products and other forms of interaction

Xylometazoline hydrochloride

Due to low systemic absorption of xylometazoline when administered intranasally, interaction with drugs administered via other routes is unlikely. No interaction studies have been performed. However, concomitant use with antihypertensive agents (e.g. methyl dopa) should be avoided due to the potential effect of Xylometazoline to increase blood pressure.

Concomitant use with medicines which potentially increase blood pressure (e. g. doxapram, ergotamin, oxytocin, or tricyclic antidepressants) should be avoided as the vasopressor effect may be increased.

Concomitant use with sympathomimetics (e.g.: pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline) can lead to additive effects on the cardiovascular system and central nervous system.

MAOIs and/or RIMAs: should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis

Moclobemide: risk of hypertensive crisis

Antihypertensives (including adrenergic neurone blockers and beta-blockers). Sudafed Plus Blocked Nose Spray may block the hypotensive effects.

Cardiac glycosides: increased risk of arrhythmias.

Ergot alkaloids (ergotamine and methysergide): increased risk of ergotism.

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension.

Dexpanthenol

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

This medicine should not be used during pregnancy, as there is not sufficient data available concerning the use of xylometazoline hydrochloride by pregnant women.

Breast-feeding

This medicine should not be used during the lactation period since it is not known whether xylometazoline hydrochloride is excreted in the breast milk.

Fertility

There is no data on the influence of this medicine on fertility.

4.7 Effects on ability to drive and use machines

This product is not expected to adversely affect the ability to drive and use machines.

4.8 Undesirable effects

The following definitions apply to the incidence of the undesirable effects:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$ to $< 1/10$)
- Uncommon ($\geq 1/1,000$ to $< 1/100$)
- Rare ($\geq 1/10,000$ to $< 1/1,000$)
- Very rare ($< 1/10,000$)
- Not known (cannot be estimated from the available data)

Tabulated list of adverse reactions

	Uncommon	Rare	Very rare	Not known
Immune system Disorders	hypersensitivity reaction (angioedema, skin rash,			
Psychiatric disorders, especially with prolonged and/or heavy use.			restlessness, insomnia, hallucinations and paranoid delusions.	irritability, anxiety, excitability
Nervous system Disorders			fatigue (drowsiness, sedation), headache, convulsions	
Cardiac disorders, especially with prolonged and/or heavy use		palpitations, tachycardia, hypertension	arrhythmias	
Respiratory, thoracic and mediastinal disorders			rebound congestion (rhinitis medicamentosa) - especially with prolonged and/or heavy use,	Sneezing, burning, irritation and dryness of the nasal mucosa.
Gastrointestinal disorders				Nausea

General disorders and administration site conditions				Tolerance with diminished effect (especially with prolonged and/or heavy use.)
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Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Xylometazoline hydrochloride

The clinical picture of intoxication with imidazole derivatives can be diverse, as phases of stimulation may alternate with periods of suppression of the central nervous system and cardiovascular system. An overdose results mainly in central nervous effects: convulsions and coma, bradycardia, apnoea, hypertension and also hypotension.

Symptoms of CNS stimulation are anxiety, agitation, hallucinations and convulsions.

Symptoms of CNS suppression are decreased body temperature, lethargy, drowsiness and coma.

The following additional symptoms may occur: miosis, mydriasis, diaphoresis, fever, pallor, cyanosis, nausea, tachycardia, bradycardia, cardiac arrhythmia, cardiac arrest, hypertension, shock-like hypotension, pulmonary oedema, respiratory disorders and apnoea.

In cases of severe overdose, intensive inpatient treatment is indicated. The administration of medicinal charcoal (absorbent), sodium sulphate (laxative) or gastric lavage (in the case of large quantities) should be performed immediately, as xylometazoline can be rapidly absorbed. In order to lower blood pressure, a non-selective alpha-adrenergic blocking agent can be given.

Vasopressor agents are contraindicated. If necessary, the following measures should be taken: fever reduction, anti-convulsive therapy and oxygen inhalation.

Dexpanthenol

Pantothenic acid and its derivatives, such as dexpanthenol, have very low toxicity. No measures are required in cases of overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal preparations; decongestants and other nasal preparations for topical use; sympathomimetics, combinations excl. corticosteroids. ATC code: R01AB06.

A rhinological agent is a combination of an alpha-sympathomimetic with a vitamin analogue for topical application to the nasal mucosa. Xylometazoline has vasoconstrictor properties and thereby causes decongestion of the blocked nose. Dexpanthenol is a derivative of the vitamin pantothenic acid, whose properties are the promotion of wound healing and protection of the mucosa.

Xylometazoline hydrochloride

Xylometazoline hydrochloride, an imidazole derivative, is an alpha -adrenergic sympathomimetic. It has a vasoconstrictor effect and thus reduces mucosal swelling. The onset of action is usually observed within 5 to 10 minutes and is evident from easier nasal breathing due to reduced mucosal swelling and improved secretion flow. Xylometazoline has a prolonged decongestant effect, lasting for up to 10 hours.

Dexpanthenol

Dexpanthenol (D-(+)-pantothenyl alcohol) is the alcoholic analogue of pantothenic acid and, due to intermediate transformation, possesses the same biological efficacy as pantothenic acid. It is bound to the right-handed D-configuration. Pantothenic acid and its salts are water-soluble vitamins which are involved as coenzyme A in numerous metabolic processes, such as the promotion of protein and corticoid synthesis and antibody production. Coenzyme A is also involved, amongst other things, in the formation of lipids via which the skin fat fulfils an important protective function, as well as for the acetylation of amino sugars that help to form various mucopolysaccharides.

Dexpanthenol induces a gene expression profile consistent with a wound healing response in human epithelium, which may support healing of the nasal mucosa in the target populations described in section 4.1. In rats with dexpanthenol deficiency, the application of dexpanthenol to the skin had a trophic effect. When used externally, dexpanthenol/panthenol can compensate for the increased pantothenic acid requirement of the damaged skin or mucous membrane.

5.2 Pharmacokinetic properties

Xylometazoline hydrochloride

Occasionally, in the case of intranasal administration, the absorbed amount of xylometazoline hydrochloride can be sufficient to induce systemic effects, e.g. on the central nervous system and the cardiovascular system.

No data is available from pharmacokinetic studies on humans for xylometazoline hydrochloride.

Dexpanthenol

Dexpanthenol is dermally absorbed and oxidised enzymatically in the organism, as well as in the skin, to pantothenic acid. The vitamin is transported in protein-bound form in the plasma. Pantothenic acid is incorporated as a key component in coenzyme A, which occurs ubiquitously in the organism. More detailed studies on the metabolism in the skin and mucous membranes are not available. 60-70% of an orally delivered dose of dexpanthenol is excreted in the urine, 30-40% in the faeces.

5.3 Preclinical safety data

Non-clinical safety data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Water for injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

30 months
After first opening of the container, the product should be used within 3 months.

6.4 Special precautions for storage

Do not store above 25°C
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

White HDPE plastic bottle with 10 ml fill volume.

The bottle is sealed with a snap-one metered 0.1 ml PP/PE/Steel pump with a white PP actuator and a HDPE pull-off cap.

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

McNeil Products Limited
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 15513/0407

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

9th February 2021

10 DATE OF REVISION OF THE TEXT

06/05/2025