Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sudafed Plus 1 mg/ml + 50 mg/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, free from particles.
pH: 5.5 - 6.4
Osmolality: 400 - 455 mOsmol/kg

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sudafed Plus 1mg/50mg/ml Nasal Spray Solution is indicated:
- for reducing the swelling of the nasal mucosa in rhinitis and as supportive treatment for healing mucous membrane lesions,
- for relief in vasomotor rhinitis (rhinitis vasomotorica),
- for the treatment of nasal respiratory obstruction after nasal surgery.

Sudafed Plus 1mg/50mg/ml Nasal Spray Solution is indicated in adults and children aged 6 years and older.

4.2 Posology and method of administration

Posology

Adults and children aged 6 years and older
The usual dose of Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is one spray into each nostril up to 3 times a day as needed.

The dosage depends on individual sensitivity and clinical efficacy.
Duration of treatment is limited to 7 days unless otherwise instructed by the doctor. Repeated use is possible only after a break of several days.

Do not exceed the recommended dose.

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

Paediatric population

The administration of the product in children under 12 years of age should be supervised by an adult. If after 3 days of treatment, no improvement or worsening of the symptoms is observed, the clinical situation should be re-evaluated. Regarding the duration of treatment in children, a doctor should always be consulted.
Sudafed Plus 1 mg/ml + 50 mg/ml nasal spray, solution is contraindicated in children under 6 years of age (see section 4.3)

Method of administration

For nasal use.

Remove the protective cap from the sprayer.
Before the first use the spray should be pressed five times until a fine spray appears.
The spray tip should be inserted upright into one nostril and the spray should be pressed and inhaled 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.
If the spray has not been used for 7 days or more, the head should be pressed twice before first re-use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
Dry inflammation of the nasal mucosa (rhinitis sicca).
History of transsphenoidal hypophysectomy or other surgical interventions which expose the dura mater.
Sudafed Plus 1mg/50mg/ml Nasal Spray Solution is contraindicated in children under 6 years of age.

4.4 Special warnings and precautions for use

This medicinal product may be used only after a careful assessment of the risks and benefits in cases of:
- patients being treated with monoamine oxidase inhibitors (MAOIs) and other drugs which potentially increase blood pressure,
- increased intraocular pressure, especially narrow-angle glaucoma,
- serious heart and circulatory diseases (e.g. coronary heart disease, hypertension),
- phaeochromocytoma,
- metabolic disorders (e.g., hyperthyroidism, diabetes),
- porphyria,
- prostate hyperplasia.

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

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

The prolonged use and overdose of decongestant sympathomimetics in particular may lead to reactive hyperaemia of the nasal mucosa. This rebound effect causes narrowing of the airways, with the consequence that the patient repeatedly uses the medicinal product until its use becomes permanent. The consequences are chronic swelling (rhinitis medicamentosa) or even atrophy of the nasal mucosa.

In less severe cases consideration can be given to discontinuing the use of the sympathomimetic in one nostril initially and after the symptoms have abated changing to the other side in order to maintain at least part of the nasal respiration.

Direct contact of the medicinal product with the eyes should be avoided.

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

4.5 Interaction with other medicinal products and other forms of interaction

Xylometazoline hydrochloride
Concomitant use of Sudafed Plus 1mg/50mg/ml Nasal Spray Solution with antihypertensive agents (e.g. methyldopa) should be avoided due to the potential effect of Xylometazoline to increase blood pressure.
Concomitant use of Sudafed Plus 1mg/50mg/ml Nasal Spray Solution with medicines which potentially increase blood pressure (e. g. z. B. doxapram, ergotamin, oxytocin, monoamine oxidase inhibitors of the tranylcypromine type 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, tuaminoheptane) can lead to additive effects on the cardiovascular system and central nervous system.

Dexpanthenol
None known.

4.6 Fertility, pregnancy and lactation

Pregnancy
Sudafed Plus 1mg/50mg/ml Nasal Spray Solution should not be used during pregnancy, as there is not sufficient data available concerning the use of xylometazoline hydrochloride by pregnant women.

Breast-feeding
Sudafed Plus 1mg/50mg/ml Nasal Spray Solution 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 Sudafed Plus 1mg/50mg/ml Nasal Spray Solution on fertility.

4.7 Effects on ability to drive and use machines

Sudafed Plus 1mg/50mg/ml Nasal Spray Solution is not expected to adversely affect the ability to drive and use machines when used as recommended.

4.8 Undesirable effects

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

- 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)
- 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, pruritus)			
Psychiatric disorders			restlessness, insomnia, hallucinations (primarily in children)	
Nervous system disorders			fatigue (drowsiness, sedation), headache, convulsions (especially in children)	
Cardiac disorders		palpitations, tachycardia, hypertension	arrhythmias	
Respiratory, thoracic and mediastinal disorders			rebound congestion, nosebleed	Sneezing, burning and dryness of the

				nasal mucosa

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 via HPRA Pharmacovigilance, website: www.hpra.ie.

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. Particularly in children, 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.

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 has epithelium-protective properties and promotes wound healing.

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

3 years

After first opening of the container, the product should be used within 6 months.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

White HDPE plastic bottle with 10 ml fill volume. Each bottle contains a minimum of 80 actuations.
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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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