SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Non-Drowsy Sudafed Decongestant Nasal Spray

Sudafed Blocked Nose Spray

Sudafed Mucus Relief 0.1% Nasal Spray

Sudafed Sinus-Ease 0.1% Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

This product is an aqueous solution of Xylometazoline Hydrochloride 0.1% w/v presented in a metered-dose pack, delivering 0.14 ml per actuation.

Excipients with known effect:
Benzalkonium chloride 0.196 mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Aqueous solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is indicated for the symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis, allergic and non-allergic rhinitis, and other upper respiratory tract allergies.

4.2 Posology and method of administration

Posology
Adults and children 12 years and over:

One spray to be expressed into each nostril 2-3 times daily, as necessary. Maximum daily dose: 3 sprays in 24 hours.

Use for more than seven consecutive days is not recommended, [See section 4.4].

Children under 12 years:

Do not give to children under 12 years of age.

The Elderly

Experience has indicated that normal adult dosage is appropriate, [See section 5.2].

Hepatic/renal dysfunction

Normal adult dosage is appropriate, [See section 5.2].

Method of administration
Nasal

4.3 Contraindications

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

Children under 12 years of age.

This product is contraindicated in individuals who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks.

This product is contraindicated in individuals with hypophysectomy or surgery exposing dura mater.

4.4 Special warnings and precautions for use

There is minimal systemic absorption with topically applied imidazoline sympathomimetics such as xylometazoline, however, this product should be used with caution in patients suffering coronary artery disease, hypertension, hyperthyroidism or diabetes mellitus. 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 hyperemia 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).

This medicine contains 1.96 mg benzalkonium chloride in each 10 ml, and 2.94 mg benzalkonium chloride in each 15 ml, which is equivalent to 0.196 mg/ml of product. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the low systemic absorption of xylometazoline when administered intra-nasally, interaction with drugs administered via other routes is considered unlikely.

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies in pregnant women. This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus.

Lactation
It is not known whether xylometazoline or its metabolites are excreted in human milk. This product should not be used during lactation unless the potential benefit to the mother outweighs the possible risks to the nursing infant.

4.7 Effects on ability to drive and use machines

It is not known if xylometazoline has an effect on the ability to drive and use machines.

4.8 Undesirable effects

Adverse Drug Reactions (ADRs) identified during clinical trials and post-marketing experience with xylometazoline are listed below by System Organ Class (SOC). The frequencies are defined in accordance with current guidance, as:

Very common ≥1/10
Common ≥1/100 and < 1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000 and <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence is unavailable, frequency category is listed as Not known.

System Organ Class (SOC)	**Frequency**	**Adverse Drug Reaction (Preferred Term)**
Nervous System Disorders	Rare Not known	Headache Burning sensation mucosal
Respiratory, Thoracic and Mediastinal Disorders	Uncommon	Epistaxis
	Not known	Nasal discomfort Nasal dryness Nasal pruritus Rhinalgia Sneezing
Gastrointestinal Disorders	Rare	Nausea
General Disorders and Administration Site Conditions	Not known	Rebound effect

Reporting of suspected adverse reactions:
Reporting 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

Symptoms

Systemic action is unlikely when applied nasally due to the local vasoconstriction that inhibits absorption. If systemic absorption does occur xylometazoline as an α_2-adrenergic agonist could be expected to produce

effects similar to those of clonidine with a short lived rise in blood pressure, followed by more prolonged hypotension and sedation.

Management
Treatment of overdose should be supportive.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal preparations, sympathomimetics, plain; ATC code: R01AA07.

It acts directly on -adrenoreceptors but does not act on ß-receptors. When used topically as a nasal decongestant, xylometazoline acts rapidly and provides long-lasting relief. Onset of action is within minutes, the decongestant effect being prolonged and lasting for up to 10 hours.

5.2 Pharmacokinetics properties

Absorption, Distribution, Biotransformation and Elimination
Little information is available concerning the absorption, distribution, Biotransformation and elimination of xylometazoline in man. Absorption into the nasal mucosal tissues is rapid.

Pharmacokinetics in Renal/Hepatic Impairment
There have been no specific studies of this product or xylometazoline in hepatic or renal impairment.

Pharmacokinetics in the Elderly
There have been no specific clinical studies of this product or xylometazoline in the elderly.

5.3 Preclinical safety data

Mutagenicity
There is insufficient information available to determine whether xylometazoline has mutagenic potential.

Carcinogenicity
There is insufficient information available to determine whether xylometazoline has carcinogenic potential.

Teratogenicity
There is insufficient information available to determine whether xylometazoline has teratogenic potential.

Fertility

No studies have been conducted in animals to determine whether xylometazoline has the potential to impair fertility. There is no information on the effects of this product on fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride solution
Disodium edetate
Sodium dihydrogen phosphate dihydrate
Sodium monohydrogen phosphate dihydrate
Sodium chloride
Sorbitol solution, 70% (Non crystalline)
Purified water

6 PHARMACEUTICAL PARTICULARS

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years.
Opened: 20 weeks after first opening, discard the bottle even if there is solution remaining.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottle of either 10 ml or 15 ml nominal fill volume.

The bottle is sealed with an integral snap-on metered 0.14 ml pump consisting of a white plastic actuator and natural polyethylene pull-off overcap.

6.6 Special precautions for disposal

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
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UK

8. MARKETING AUTHORIZATION NUMBER(S)

PL 15513/0074

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 April 1999/04 August 2011

10 DATE OF REVISION OF THE TEXT

22/12/2022