Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sudafed 0.1% w/v Nasal spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The Solution contains 0.1% w/v Xylometazoline Hydrochloride. Each metered spray (0.14 ml) delivers 140 micrograms of xylometazoline hydrocholoride

Excipients: The solution contains 0.040% w/v benzalkonium chloride solution and 2 % w/v sorbitol liquid.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal spray solution (nasal spray)
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Sudafed Nasal Spray 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

Adults and children 12 years and over:
Nasal. One spray to be expressed into each nostril 2-3 times daily, as necessary.
Maximum daily dose: 3 Sprays per nostril.
Do not exceed the stated dose.
Use for more than seven consecutive days is not recommended. [See section 4.4].

Children aged 6 to 12 years:
Nasal. One spray to be expressed into each nostril 2-3 times daily, as necessary.
Maximum daily dose: 3 Sprays per nostril.
Do not exceed the stated dose.
Consult a doctor or pharmacist before use. Use only when simple measures have failed to bring adequate relief. Use for more than five consecutive days is not recommended. [See section 4.4].

Children under 6 years:
Do not give SUDAFED decongestant Nasal Spray to children under 6 years of age [see section 4.3].

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].

4.3 Contraindications

Sudafed Nasal Spray is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

Sudafed Nasal Spray is contraindicated in individuals who are taking or have taken, monoamine oxidase inhibitors within the preceeding two weeks.

Sudafed Nasal Spray is contraindicated in individuals with hypophysectomy or surgery exposing dura mater.

Sudafed Nasal Spray is contraindicated for use in children under the age of 6 years.

4.4 Special warnings and precautions for use

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

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

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).

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

Sorbitol E420 – Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Children aged 6 to 12 years: Consult a doctor or pharmacist before using this product. Do not use with other cough and cold medicines.

4.5 Interaction with other medicinal products and other forms of interactions

Due to the low systematic absorption of xylometazoline when administered intranasally, interaction with drugs administered via other routes is considered unlikely.

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

No prospective pharmaco-epidemiological studies have been conducted to examine the effects of xylometazoline nasal spray in pregnancy. The safety of use in pregnancy has not been established.

Congenital defects have been documented in an uncontrolled retrospective review, in babies of women exposed to xylometazoline during the first 3 months of pregnancy. A cause and effect association was not established.

It is not known whether xylometazoline or its metabolites are excreted in human milk.

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or 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, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <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	Not known	Burning sensation mucosal
Respiratory, Thoracic and Mediastinal Disorders	Uncommon Not known	Epistaxis Nasal discomfort Nasal dryness Nasal pruritus Rhinalgia Sneezing
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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Symptoms and signs
Systemic action is unlikely when applied nasally due to the local vasoconstriction that inhibits absorption. If systemic absorption does occur xylometazoline as an a2- 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.

Treatment
Treatment of overdose should be supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Xylometazoline is a sympathomimetic amine of the imidazoline class.
It act directly on a-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 12 hours.

5.2 Pharmacokinetic properties

Absorption, Distribution, Metabolism and Elimination
Little information is available concerning the absorption, distribution, metabolism 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 Sudafed Nasal Spray or xylometazoline in hepatic or renal impairment.

Pharmacokinetics in the Elderly
There have been no specific clinical studies of Sudafed Nasal Spray 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 Sudafed Nasal Spray on fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride solution
Disodium edetate
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Sorbitol E420, Liquid (Non-crystallising)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container in the outer carton.

6.5 Nature and contents of container

Type III amber glass bottle of either 10 ml or 15 ml minimal fill volume.
The bottle is sealed with an integral snap-on metered 0.14 ml pump consisting of a white plastic (composed of polyethylene, polypropylene, polyoxymethylene parts and polyethylene/butadiene seal) actuator and natural polyethylene pull off overcap.

Each 10 ml bottle contains an average of 35 doses.
Each 15 ml bottle contains an average of 53 doses.

Not all pack sizes may be marketed.

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

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th June 2003

Date of last renewal: 30th June 2008

10 DATE OF REVISION OF THE TEXT

July 2021