

# 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 hydrochloride.

Excipient: the solution contains 0.04% w/v benzalkonium chloride solution.

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.

Use for more than seven consecutive days is not recommended. [See Undesirable Effects]

#### 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.

Use only when simple measures have failed to bring adequate relief. Use for more than five consecutive days is not recommended. [See Undesirable Effects]

#### Children under 6 years:

SUDAFED decongestant Nasal Spray is not recommended for children under 6 years of age [see section 4.3]

#### The Elderly

Experience had indicated that normal adult dosage is appropriate, [See Pharmacokinetics in Elderly]

#### Hepatic/renal dysfunction

Normal adult dosage is appropriate, [See Pharmacokinetics]

### 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 preceding 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**

There is minimal systematic 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.

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 is an irritant which may cause skin reactions and may cause bronchospasms

Sorbitol E420 – If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine

Do not exceed the stated dose.

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 interaction**

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 and administration of xylometazoline during pregnancy should be avoided.

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 the human milk.

#### **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**

Xylometazoline nasal preparations are generally well tolerated following short-term use and local side effects are mild and infrequent. Localised burning, stinging, itching, soreness, dryness or irritation and sneezing may occur occasionally.

Rebound congestion has been reported occasionally, particularly following longer-term use of xylometazoline.

## 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  $\alpha_2$ -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.

### Treatment

Treatment of overdosage should be supportive.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Xylometazoline is a sympathomimetic amine of the imidazoline class.

It act directly on  $\alpha$ -adrenoreceptors but does not act on  $\beta$ -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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

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

## 8 MARKETING AUTHORISATION NUMBER

PA0823/033/001

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

Date of first authorisation: 30<sup>th</sup> June 2003

Date of last renewal: 30<sup>th</sup> June 2008

**10 DATE OF REVISION OF THE TEXT**

August 2013