

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Non – Drowsy Sudafed Decongestant 30mg/5ml Syrup

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of Non-Drowsy Sudafed Decongestant Syrup contains 30.0 mg pseudoephedrine hydrochloride.

Excipients: Each 5 ml also includes sucrose 3.5g, methyl parahydroxybenzoate (E218) 5mg, ponceau 4R (E124) 1.50mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Syrup.

A clear, red liquid with a characteristic raspberry odour and taste.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

This medicine is a decongestant of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses and is indicated for the symptomatic relief of nasal congestion in conditions such as allergic rhinitis, vasomotor rhinitis, the common cold and influenza.

### 4.2 Posology and method of administration

Posology:

#### Adults and Children aged 12 years and over

10 ml syrup every 4-6 hours, up to four times a day.

Maximum daily dose: 40 ml (240 mg pseudoephedrine).

#### Children 6<12 years

5 ml syrup every 4-6 hours, up to four times a day.

Maximum daily dose: 20ml. (120 mg pseudoephedrine).

Use only when simple measures have failed to provide adequate relief.

#### Children under 6 years

This medicine is contraindicated in children under the age of 6 years [See Section 4.3].

#### Use in the Elderly

There have been no specific studies of this medicine in the elderly. Experience has indicated that normal adult dosage is appropriate.

#### Hepatic Dysfunction

Caution should be exercised when administering this medicine to patients with severe hepatic impairment.

#### Renal Dysfunction

Caution should be exercised when administering this medicine to patients with mild to moderate renal impairment.

**Duration of use:**

Patients should be advised not to use this product for more than 5 days and to seek medical advice if symptoms persist. Parents or carers of children aged 6-12 years of age should seek medical attention if the child's condition deteriorates during treatment.

Do not exceed the stated dose.

Keep out of the sight and reach of children

**Method of Administration:**

For oral use

**4.3 Contraindications**

This medicine is contraindicated in individuals who have previously exhibited hypersensitivity to pseudoephedrine or to any of the excipients listed in Section 6.1

This medicine is contraindicated in individuals with cardiovascular disease including hypertension and in those who are taking beta blockers (see section 4.5).

This medicine is contraindicated in individuals who are taking or have taken monoamine oxidase inhibitors (MAOIs) within the preceding two weeks. The concomitant use of pseudoephedrine and this type of product may cause a rise in blood pressure or hypertensive crisis.

This medicine is contraindicated in individuals who have diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma or severe renal impairment.

This medicine is contraindicated in individuals who are currently taking other sympathomimetic decongestants.

This medicine is contraindicated in patients at risk of developing respiratory failure.

This medicine not to be used in children under the age of 6 years.

The antibacterial agent furazolidone is known to cause a dose-related inhibition of monoamine oxidase. Although there are no reports of hypertensive crises caused by the concurrent administration of this medicine and furazolidone they should not be taken together.

**4.4 Special warnings and precautions for use**

Although pseudoephedrine has virtually no pressor effects in normotensive patients, this medicine should be used with caution in patients taking tricyclic antidepressants or other sympathomimetic agents (such as appetite suppressants and amphetamine-like psychostimulants). The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

If any of the following occur, this medicine should be stopped:

- Hallucinations
- Restlessness
- Sleep disturbances

This medicine should be used with caution in patients with urinary retention due to prostatic enlargement. There have been no specific studies of this medicine in patients with hepatic and/or renal dysfunction. Caution should be exercised when using the product in the presence of hepatic impairment or mild to moderate renal impairment.

Use with caution in occlusive vascular disease.

This product may act as a cerebral stimulant giving rise to hyperpyrexia, tremor and epileptiform convulsions.

Patients with rare hereditary problems of fructose intolerance, glucose – galactose malabsorption or sucrase – isomaltase insufficiency should not take this medicine.

Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose.

Do not take with any other cough and cold medicine.

Consult a pharmacist or other healthcare professional before use in children aged 6 to 12 years.

## 4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of this medicine with tricyclic antidepressants, or with other sympathomimetic agents (such as appetite suppressants and amphetamine-like psychostimulants), may cause a rise in blood pressure.

Pseudoephedrine exerts its vasoconstricting properties by stimulating  $\alpha$ -adrenergic receptors and displacing noradrenaline from neuronal storage sites. Since MAOIs impede the metabolism of sympathomimetic amines and increase the store of releasable noradrenaline in adrenergic nerve endings, MAOIs may potentiate the pressor effect of pseudoephedrine.

MAOIs and/or RIMAs: this medicine should not be given to patients treated with MAOIs or within 14 days of stopping treatment as there is an increased risk of hypertensive crisis.

Moclobemide: risk of hypertensive crisis

The antibiotic furazolidone is a monoamine oxidase inhibitor. Therefore it should not be taken with this medicine (see Section 4.3).

Because of its pseudoephedrine content, this medicine may antagonise the hypotensive action of antihypertensive drugs which interfere with sympathetic activity including bretylium, bethanidine, guanethidine, reserpine, debrisoquine, methyldopa, adrenergic neurone blockers and betablockers.

Oxytocin: risk of hypertension

Cardiac glycosides: increased risk of dysrhythmias

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism

Anticholinergic drugs: enhances effects of anticholinergic drugs (such as TCAs)

Caution should be exercised during use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane as they may provoke or worsen ventricular arrhythmias.

## 4.6 Fertility, pregnancy and lactation

### Pregnancy

There are no adequate and well-controlled clinical 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.

Although pseudoephedrine has been in widespread use for many years without apparent ill consequence, there are no specific data on its use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing foetus.

Fertility

There is no information on the effect of this medicine on human fertility.

Breast-feeding

This medicine should not be used during lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the nursing infant.

Pseudoephedrine distributes into and is concentrated in breast milk.

**4.7 Effects on ability to drive and use machines**

This medicine has no or negligible influence on the ability to drive and use machines

**4.8 Undesirable effects**

The safety of pseudoephedrine from clinical trial data is based on 6 randomised, placebo-controlled single dose clinical trials and 6 randomised, placebo-controlled multiple dose trials for the treatment of nasal congestion with allergic rhinitis or common cold or prevention of sinus symptoms/infection after a natural cold.

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with pseudoephedrine are listed below by System Organ Class (SOC). The frequencies are defined according to the following convention:

- 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, when available, or 2) when incidence cannot be estimated, frequency category is listed as ‘Not known’.

System Organ Class (SOC)	Frequency	Adverse drug reaction (Preferred Term)
Immune system disorders	Not known	Hypersensitivity – cross sensitivity may occur with other sympathomimetics
Psychiatric Disorders	Common	Insomnia Nervousness
	Rare	Hallucination
	Not known	Agitation Anxiety Delusion Euphoric mood Irritability Restlessness Sleep disorder
Nervous System Disorders	Very common	Headache
	Common	Dizziness
	Not known	Psychomotor hyperactivity
Cardiac Disorders	Not known	Arrhythmia Palpitations Tachycardia
Vascular Disorders	Not known	Hypertension

Gastrointestinal Disorders	Common	Dry mouth Nausea
	Not known	Vomiting
Skin and Subcutaneous Tissue Disorders	Not known	Rash (with or without irritation)
Renal and urinary Disorders	Not known	Dysuria Urinary retention (in male patients in whom prostatic enlargement could have been an important predisposing factor)
General Disorders and administration site conditions	Not known	Feeling jittery

**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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**4.9 Overdose**

**Signs and symptoms:**

Overdosage may result in:  
Metabolism and nutrition disorders: hyperglycaemia, hypokalaemia

Psychiatric disorders: CNS stimulation, insomnia; irritability, restlessness, anxiety, agitation; confusion, delirium, hallucinations, psychoses

Nervous system disorders: convulsions, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children

Eye disorders: mydriasis

Cardiac disorders: palpitations, tachycardia, reflex bradycardia, supraventricular and ventricular arrhythmias, dysrhythmias, myocardial infarction

Vascular disorders: hypertension, hypertensive crisis

Gastrointestinal disorders: nausea, vomiting, ischaemic bowel infarction

Musculoskeletal and connective tissue disorders: rhabdomyolysis

Renal and urinary disorders: acute renal failure, difficulty in micturition

**Treatment:** Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

#### Pharmacotherapeutic Group: Respiratory System

ATC Code: R01BA02

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation in systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.

Pseudoephedrine produces its decongestant effect within 30 minutes which lasts for at least 4 hours.

### 5.2 Pharmacokinetic properties

In healthy adult volunteers, the administration of 60 mg pseudoephedrine resulted in a peak plasma concentration (C<sub>max</sub>) of approximately 180 ng/ml occurring at about 2 hours (T<sub>max</sub>) post dose. The plasma half-life was approximately 5.5 hours (urine pH maintained between 5.0-7.0).

The plasma half-life of pseudoephedrine is markedly decreased by acidification of the urine and increased by alkalinization. Pseudoephedrine is partly metabolised in the liver by N-demethylation to norpseudoephedrine, an active metabolite. Excretion is mainly via the urine, 55% to 75% of a dose is excreted unchanged.

In a limited study, three mothers nursing healthy infants were given an antihistamine-decongestant preparation containing 60 mg of pseudoephedrine and 2.5 mg of triprolidine. Milk concentrations of pseudoephedrine were higher than plasma levels in all three patients, with peak milk concentrations occurring at 1.0–1.5 hours. The investigators calculated that 1000 ml of milk produced during 24 hours would contain approximately 0.5%–0.7% of the maternal dose. However, following a single-blind, crossover study of a single dose of pseudoephedrine 60 mg vs. placebo conducted in 8 lactating mothers, and assuming maternal intake of 60 mg pseudoephedrine hydrochloride four times daily, the estimated infant dose of pseudoephedrine based on AUC and an estimated milk production rate of 150 ml/kg/day was 4.3% (95% CI, 3.2, 5.4%; range 2.2 to 6.7%) of the weight-adjusted maternal dose.

### 5.3 Preclinical safety data

The active ingredient of this medicine is a well-known constituent of medicinal products and its safety is well documented. The results of preclinical studies do not add anything of relevance for therapeutic purposes.

There is insufficient information available to determine whether pseudoephedrine has mutagenic or carcinogenic potential.

Systemic administration of pseudoephedrine, up to 50 times the human daily dosage in rats and up to 35 times the human daily dosage in rabbits, did not produce teratogenic effects.

Systemic administration of pseudoephedrine in rats, up to 7 times the human daily dosage in females and 35 times the human daily dosage in males, did not impair fertility nor alter foetal morphological development and survival.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid monohydrate

Sucrose

Glycerol

Methyl parahydroxybenzoate (E218)

Sodium benzoate (E211)

Ponceau 4R (E124)  
Flavour, raspberry essence no. 1  
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 in the original container.

**6.5 Nature and contents of container**

100ml amber glass bottles with metal roll on closures or HDPE screw caps, each cap containing a Saran or Steran (PVDC)-lined wad or polyethylene/expanded polyethylene laminated wad.

100ml amber glass bottles with a 3 piece plastic child resistant, tamper evident closure fitted with a polyvinylidene chloride (PVDC) faced wad or polyethylene/expanded polyethylene laminated wad.

A measuring spoon is supplied with each bottle.

**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**

PA0823/009/001

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

Date of first authorisation: 23<sup>rd</sup> June 1978

Date of last renewal: 1<sup>st</sup> April 2009

**10 DATE OF REVISION OF THE TEXT**

March 2016