Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film-Coated tablet contains Pseudoephedrine Hydrochloride 60.0 mg.

Excipients: Contains Lactose Monohydrate 112.0mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Reddish-brown, circular, biconvex, film coated tablets embossed 'SUDAFED' on one side.

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
The usual dose is 1 tablet (60 mg) every four to six hours, up to four times a day.
Maximum daily dose: 240 mg pseudoephedrine

Children under 12 years
This medicine is contraindicated in children under the age of 12 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.

Method of administration:
For oral use.

4.3 Contraindications

This medicine is contra-indicated in individuals with known hypersensitivity to pseudoephedrine or any of the excipients listed in section 6.1.

This medicine is contra-indicated 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 and/or hypertensive crisis.

This medicine is contra-indicated 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 have diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, or severe renal impairment.

This medicine is contra-indicated in individuals at risk of developing respiratory failure.

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

This medicine is contra-indicated in children under 12 years of age.

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 antihypertensive agents, tricyclic antidepressants, or other sympathomimetic agents (such as appetite suppressants and amphetamine-like psychostimulants). The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.

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

Severe Skin reactions
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued and appropriate measures taken if needed.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately if signs or symptoms of PRES/RCVS develop.

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 severe hepatic impairment or mild to moderate renal impairment.

Patients with difficulty in urination and/or enlargement of the prostate should be advised to consult a physician before using this product.

Patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician.

Use with caution in occlusive vascular disease.

This product may act as a cerebral stimulant giving rise to hyperpyrexia, tremor and epileptiform convulsions. Care should be taken when used in epileptic patients.

Pseudoephedrine may induce positive results in certain anti-doping tests.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

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

MAOIs and/or RIMAs: Pseudoephedrine exerts its vasoconstricting properties by stimulating α-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. 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

Antihypertensives: Because of their pseudoephedrine content, this medicine may antagonise the hypotensive action of antihypertensive drugs which interfere with sympathetic activity including bretylium, betanidine, guanethidine, reserpine, debrisoquine, methyldopa, adrenergic neurone blockers and beta blockers.

Oxytocin: risk of hypertension

Cardiac glycosides: increased risk of dysrhythmias

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

Anticholinergic drugs: The effects of anti-cholinergics e.g., some psychotropic drugs (such as tricyclic antidepressants) and atropine, may be potentiated by this product giving rise to tachycardia, mouth dryness, gastrointestinal disturbances, e.g., colic, urinary retention and headache.

Anaesthetic agents: Concurrent use with halogenated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane 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.

Fertility

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

Breastfeeding

Non-Drowsy SUDAFED Decongestant Tablets should not be used during lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the breastfeeding infant.

Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother.

4.7 Effects on ability to drive and use machines

This product may have a minor influence on the ability to drive and use machines.

This product may cause dizziness. Patients should be cautioned about engaging in activities such as driving a car or operating machinery, until they have established their own response to the drug.

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 Hallucination, visual

		Irritability Restlessness Sleep disorder
Nervous System Disorders	Very common	Headache
	Common	Dizziness
	Not known	Cerebrovascular accident (stroke without known pre-existing risk factors) Paraesthesia Posterior reversible encephalopathy syndrome (PRES) / Reversible cerebral vasoconstriction syndrome Psychomotor hyperactivity Somnolence Tremor
Eye Disorders	Not known	Ischaemic optic neuropathy
Cardiac Disorders	Not known	Arrhythmia Myocardial infarction/Myocardial ischaemia Palpitations Tachycardia
Vascular Disorders	Not known	Hypertension
Gastrointestinal Disorders	Common	Dry mouth Nausea
	Not known	Ischaemic colitis Vomiting
Skin and Subcutaneous Tissue Disorders	Not known	Angioedema Pruritus Rash Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP)
Renal and urinary Disorders	Not known	Dysuria Urinary retention (in male patients in whom prostatic enlargement could have been an important predisposing factor)

No differences between adult and paediatric safety profiles have been identified.

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

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: seizures, 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

Management
Necessary measures should be taken to support respiration and control convulsions. 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

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_{max}) of approximately 180 ng/ml occurring at about 2 hours (T_{max}) 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 pre-clinical 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

Lactose monohydrate

Cellulose microcrystalline
Pregelatinised maize starch
Silica colloidal anhydrous
Magnesium stearate

Film Coat
Opadry OY-S-9473

Opadry OY-S-9473 contains:
Hypromellose
Red Iron Oxide, E172
Talc
Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container to protect from light.

6.5 Nature and contents of container

12 and 24 - PVC/PVDC/Aluminium foil blister packs.

100 - High density polyethylene containers with low density polyethylene tamper evident snap-on-lids.

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
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8 MARKETING AUTHORISATION NUMBER

PA0330/057/002

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10 DATE OF REVISION OF THE TEXT

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