SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sudafed Decongestant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pseudoephedrine hydrochloride 60.00 mg.
Excipients with known effects:
Lactose
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Reddish-brown, round, biconvex film-coated tablets, with ‘Sudafed’ on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sudafed Decongestant Tablets 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 conditions such as allergic rhinitis, vasomotor rhinitis, the common cold and influenza.

4.2 Posology and method of administration

Posology

Adults and Children over 12 years

1 tablet every 4 - 6 hours up to 4 times a day.

Use in the Elderly

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

Hepatic Dysfunction

Caution should be exercised when administering Sudafed Decongestant Tablets to patients with severe hepatic impairment.

Renal Dysfunction

Caution should be exercised when administering Sudafed Decongestant Tablets to patients with moderate renal impairment.

Method of Administration

For oral use

4.3 Contraindications

Sudafed Decongestant Tablets are contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of the excipients listed in section 6.1.
Concomitant use of other sympathomimetic decongestants, beta-blockers (see section 4.5) or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment (see section 4.5). The concomitant use of MAOIs may cause a rise in blood pressure and/or hypertensive crisis (see section 4.5).

Cardiovascular disease including hypertension
Diabetes mellitus
Phaeochromocytoma
Hyperthyroidism
Closed angle glaucoma
Severe acute or chronic kidney disease/renal failure

4.4 Special warnings and precautions for use

Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician.

Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment and in occlusive vascular disease.

If any of the following occur, this product 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.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

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

4.5 Interaction with other medicinal products and other forms of interaction

- MAOIs and/or RIMAs: Pseudoephedrine exerts its vasoconstricting properties by stimulating α -adrenergic receptors and displacing noradrenaline from neuronal storage sites. Since monoamine oxidase inhibitors (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 product should not be used in patients taking monoamine inhibitors or within 14 days of stopping treatment as there is an increased risk of hypertensive crisis.

- Moclobemide: Risk of hypertensive crisis.

- Antihypertensives: Because of its pseudoephedrine content, this product may partially reverse the hypotensive action of antihypertensive drugs which interfere with sympathetic activity including bretylium, betanidine, guanethedine, debrisoquine, methyldopa, adrenergic neurone blockers and beta-blockers.

- Cardiac glycosides: Increased risk of dysrhythmias.
- Ergot alkaloids (ergotamine & methysergide): Increased risk of ergotism.
- Appetite suppressants and amphetamine-like psychostimulants: Risk of hypertension.
- Oxytocin: Risk of hypertension.
- Anticholinergic drugs: Enhances effects of anticholinergic drugs (such as Tricyclic antidepressants).
- 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

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 breastfeeding infant.

Pregnancy

There are no adequate and well-controlled studies in pregnant women.
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.

Breastfeeding

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

None known

4.8 Undesirable effects

Clinical Trial Data

The safety of pseudoephedrine from clinical trial data is based on data from 6 randomised, placebo-controlled single dose clinical trials and 6 randomised, placebo-controlled multiple dose clinical trials for the treatment of nasal congestion with allergic rhinitis or common cold or prevention of sinus symptoms/infection after a natural cold.
Table 1 includes adverse events from clinical trial and post-marketing experience. Adverse events included from clinical trials are those that

occurred where greater than one event was reported, and the incidence was greater than placebo and in 1% of patients or more.

Post-marketing Data

Adverse drug reactions (ADRs) identified during post-marketing experience with pseudoephedrine are included in Table 1 below.

The adverse drug reactions are ranked by frequency, using 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)

Table 1: Adverse Reactions Reported in Clinical Trials and Post-marketing Experience

System Organ Class	**Adverse Reactions**			
	Frequency Category			
	Very Common (≥1/10)	**Common** (≥1/100 to <1/10)	**Rare** ≥1/10,000 to <1/1,000	**Not known**
Immune System Disorders				Hypersensitivity – cross-sensitivity may occur with other sympathomimetics
Psychiatric Disorders		Insomnia Nervousness		Anxiety Euphoric mood Excitability Hallucinations Irritability Paranoid delusions Restlessness Sleep disorder
Nervous System Disorders	Headache	Dizziness		Cerebrovascular accident Paraesthesia Posterior reversible encephalopathy syndrome (PRES) (see section 4.4) Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4) Psychomotor hyperactivity Somnolence Tremor

Eye Disorders				Ischaemic optic neuropathy
Cardiac Disorders				Dysrhythmias Myocardial infarction/myocardial ischaemia Palpitations Tachycardia
Vascular Disorders				Hypertension
Gastrointestinal Disorders		Dry mouth Nausea		Ischaemic colitis Vomiting
Skin and Subcutaneous Tissue Disorders				Angioedema Pruritus Rash Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP)
Renal and Urinary Disorders				Dysuria Urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor)

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Overdose may result in:

Hyperglycaemia, hypokalaemia CNS stimulation, insomnia; irritability, restlessness, anxiety, agitation; confusion, delirium, hallucinations, psychoses, seizures, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children, mydriasis, palpitations, tachycardia, reflex bradycardia, supraventricular and ventricular arrhythmias, dysrhythmias, myocardial infarction, hypertension, vomiting, ischaemic bowel infarction, acute renal failure, difficulty in micturition.

Management
Necessary measures should be taken to maintain and 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.

5.1 Pharmacodynamic properties

Sympathomimetics, 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.

5.2 Pharmacokinetic properties

Pseudoephedrine is rapidly and completely absorbed after oral administration. After an oral dose of 180mg to man, peak plasma concentrations of 500-900ng/ml were obtained about 2 hours post dose. The plasma half-life was about 5.5 hours and was increased in subjects with alkaline urine and decreased in subjects with acid urine. The only metabolism was N-demethylation which occurred to a small extent. Excretion was mainly via the urine.

5.3 Preclinical safety data

The active ingredient of Sudafed Decongestant Tablets 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Pregelatinised maize starch
Cellulose microcrystalline
Magnesium Stearate
Silica colloidal

Film Coat:

Opadry OY-S-9473

Opadry OY-S-9473 contains:
Hypromellose
Red iron oxide (E172)
Talc

Polyethylene glycol 400

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

Store in the original package to protect from moisture.

6.5 Nature and contents of container

12 tablets in PVC/PVDC/Aluminium foil blister packs.

6.6 Special precautions for disposal

No special requirements for disposal.

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

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
Foundation Park
Roxborough Way
Maidenhead
Berkshire SL6 3UG
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 15513/0024

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/03/1997 / 28/07/2004

10 DATE OF REVISION OF THE TEXT

18/05/2025