NEW ZEALAND DATA SHEET

1 PRODUCT NAME
Sudafed® Sinus and Nasal Decongestant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Sudafed® Sinus and Nasal Decongestant contain pseudoephedrine hydrochloride 60mg.

Sudafed® Sinus and Nasal Decongestant also contains lactose and sugars.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM
Sudafed® Sinus and Nasal Decongestant tablets are white, biconvex, round and uncoated. They are embossed with 'S7A' and scored on the upper face, and the bottom face is plain.

Do not halve tablet.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Sudafed® Sinus and Nasal Decongestant provides symptomatic relief of sinus and nasal congestion due to allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis, sinusitis, the common cold and flu.

4.2 Dose and method of administration
The recommended dose of Sudafed® Sinus and Nasal Decongestant for adults and children 12 years and over is 1 tablet 3 to 4 times a day. Do not halve tablet.

Sudafed® Sinus and Nasal Decongestant should not be used for children under 12 years.

No more than 4 tablets should be taken in 24 hours.

Sudafed® Sinus and Nasal Decongestant should not be used for more than 7 days except on medical advice.

4.3 Contraindications
This product is contraindicated for use in patients with the following conditions:

- known hypersensitivity or idiosyncratic reaction to pseudoephedrine (or substances of a similar chemical structure) or any of the other ingredients in the product.
- uncontrolled hypertension or severe coronary artery disease
- taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.

Refer to '4.5 Interactions with other medicines and other forms of interactions' for additional information.

4.4 Special warnings and precautions for use
Identified precautions

Use in caution patients with the following conditions:

- Hepatic impairment or severe hepatic dysfunction
- Renal impairment or severe renal dysfunction
- Hypertension

- Hyperthyroidism
- Diabetes mellitus
- Coronary heart disease
- Ischaemic heart disease
- Glaucoma
- Prostatic hypertrophy

Effects on sleep
Pseudoephedrine may cause sleeplessness if taken up to several hours before going to bed.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Discontinue the product and seek medical advice if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Skin reactions
If formation of small pustules occur, with or without pyrexia or erythema, then treatment with pseudoephedrine should be discontinued and a physician should be consulted.

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

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

Use in the elderly
No data available.

Paediatric use
Do not use in children under 12 years.

Effects on laboratory tests
No data available.

4.5 Interaction with other medicines and other forms of interaction
The following interactions with pseudoephedrine have been noted:
- Antidepressant medication eg tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis
- Other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects
- Antihypertensives e.g. beta-blockers, methyldopa – pseudoephedrine may antagonize the effect of certain classes of antihypertensives and cause an increase in blood pressure
- Urinary acidifiers enhance elimination of pseudoephedrine
- Urinary alkalinisers decrease elimination of pseudoephedrine.

4.6 Fertility, pregnancy and lactation

Effects on fertility
No data available.

Use in pregnancy
Pseudoephedrine has been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals are inadequate or may be lacking, but available data shows no evidence of an increased occurrence of foetal damage.

Pseudoephedrine should be used in pregnancy only if the potential benefits to the patient are weighed against the possible risk to the foetus.

Use in lactation
Pseudoephedrine is secreted in breast milk in small amounts. It has been estimated that 0.5% to 0.7% of a single dose of pseudoephedrine ingested by the mother will be excreted in the breast milk over 24 hours. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

4.7 Effects on ability to drive and use machines
No data available.

4.8 Undesirable effects
Adverse effects include:

- Cardiovascular stimulation – elevated blood pressure, palpitations,
- Tachycardia or arrhythmias
- CNS stimulation – headache, restlessness, feeling jittery, insomnia, anxiety, euphoric mood, tremor and (rarely) hallucinations
- Psychomotor hyperactivity (in the paediatric population)
- Skin rashes, dysuria and urinary retention
- Hypersensitivity.

Children and the elderly are more likely to experience adverse effects than other age groups.

Post-marketing Data
Additional adverse drug reactions (ADRs) identified during post-marketing experience with pseudoephedrine are included in table below. The frequencies are provided 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 <1/1,1000
Very rare	<1/10,000

In the following table the ADRs are presented with ADR frequency categories estimated from spontaneous reporting rates where numerator represents total number of reported Company AEs under given PT or medical concept and the denominator represents exposure data calculated from sales data.

Adverse Drug Reactions Identified During Post-Marketing Experience with Pseudoephedrine by Frequency Category Estimated from Spontaneous Reporting Rates

System Organ Class Frequency Category	Adverse Event Preferred Term
Immune System Disorders	
Very rare	*Hypersensitivity*
Psychiatric Disorders	
Very rare	*Anxiety*
Very rare	*Euphoric mood*
Very rare	*Hallucination*
Very rare	*Hallucination, visual*
Very rare	*Restlessness*
Nervous System Disorders	
Very rare	*Cerebrovascular accident**
Very rare	*Headache*
Very rare	*Somnolence*
Very rare	*Paraesthesia*
Very rare	*Psychomotor hyperactivity*
Very rare	*Tremor*
Very rare	*Posterior Reversible Encephalopathy Syndrome*
Very rare	*Reversible Cerebral Vasoconstriction Syndrome*
Eye Disorders	
Unknown	*Ischaemic optic neuropathy*
Cardiac Disorders	
Very rare	*Arrhythmia*
Very rare	*Myocardial infarction**
Very rare	*Palpitations*
Very rare	*Tachycardia*
Gastrointestinal Disorders	
Very rare	*Colitis ischaemic*
Very rare	*Vomiting*
Skin and Subcutaneous Tissue Disorders	
Very rare	*Pruritus*
Very rare	*Acute generalised exanthematous pustuloisis*
Very rare	*Angioedema*
Very rare	*Rash*

Renal and Urinary Disorders	
Very rare	*Dysuria*
Very rare	*Urinary retention*
Investigations	
Very rare	*Blood pressure increased*

* These events have been reported very rarely in post-marketing safety. A recent postauthorisation safety study (PASS) did not provide any evidence of increased risk of myocardial infarction or cerebrovascular accident associated with the use of vasoconstrictors for nasal decongestion, including pseudoephedrine.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose
Overdosage with paracetamol if left untreated can result in severe, sometimes fatal liver damage, and rarely, acute renal tubular necrosis.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Mechanism of action
Pseudoephedrine has direct and indirect sympathomimetic activity and is an effective decongestant in the upper respiratory tract. It is a stereoisomer of ephedrine and has a similar action, but has been found to have less pressor activity and fewer CNS effects.

Sympathomimetic agents are used as nasal decongestants to provide symptomatic relief. They act by causing vasoconstriction resulting in redistribution of local blood flow to reduce oedema of the nasal mucosa, thus improving ventilation, drainage and nasal stuffiness.

Clinical trials
The safety of pseudoephedrine from clinical trial data is based on data from 6 randomized, placebo-controlled single dose clinical trials and 6 randomized, 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.

The following table includes adverse events that occurred where greater than one event was reported, and the incidence was greater than placebo and in 1% of patients or more.

AEs Reported by ≥1% of Pseudoephedrine-treated Subjects in 12 Randomized Placebo-Controlled Clinical Trials

System Organ Class Preferred Term	Pseudoephedrine 60 mg single-dose (N=229) % (frequency)	Pseudoephedrine 60-120 mg multidose (N=496) % (frequency)	Placebo (N=709) % (frequency)
Gastrointestinal Disorders			
Dry mouth	-	3.6 (Common)	1.0 (Common)
Nausea	4.4 (Common)	0.2	1.3 (Common)
Nervous System Disorders *Dizziness*	5.2 (Common)	0.4	2.0 (Common)
Psychiatric Disorders			
Insomnia	2.2 (Common)	2.6 (Common)	0.3
Nervousness	2.6 (Common)	1.8 (Common)	0.7

5.2 Pharmacokinetic properties

Absorption

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite. It has a half-life of about 5-8 hours; elimination is enhanced and half-life reduced accordingly in acid urine.

Distribution

Small amounts are distributed into breast milk.

Metabolism

It has a half-life of about 5-8 hours; elimination is enhanced and half-life reduced accordingly in acid urine.

Excretion

It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite.

5.3 Preclinical safety data

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sudafed® Sinus and Nasal Decongestant contains lactose, magnesium stearate, povidone, maize starch.

6.2 Incompatibilities

Incompatibilities were either not assessed or not identified as part of the registration of this medicine. Refer to Section 4.5 – Interactions with other medicines and other forms of interactions.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of container
Blister packs of 12 tablets.

6.6 Special precautions for disposal
Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE
Class C3 Controlled Drug

8. SPONSOR
JNTL Consumer Health (New Zealand) Limited
PO Box 147247
Ponsonby
Auckland 1144

9. DATE OF FIRST APPROVAL
Date of publication in the New Zealand Gazette of consent to distribute the medicine: 12 April 2024

10. DATE OF REVISION OF THE TEXT
12 April 2024

Summary table of changes

Section changed	Summary of new information
Whole data sheet	New data sheet