NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Sudomyl, Tablet, 60 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name and strength of the active substance

Pseudoephedrine Hydrochloride 60mg

Excipient(s) with known effect

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral - tablet

Presentation

Sudomyl is a white biconvex circular tablet with a diameter of about 8.5 mm.

Each tablet contains 60mg of Pseudoephedrine Hydrochloride.

Tablets cannot be halved.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sudomyl is indicated for the effective relief of

- runny nose;
- sinus and nasal congestion; and
- sinus pain due to congestion.

Sudomyl reduces the swelling and secretions in the nose and sinuses, allowing the patient to breathe more easily. It relieves the pressure behind the nose and eyes, which is the cause of sinus pain and headache.

4.2 Dose and method of administration

Adults and children over 12 years: One tablet if necessary, up to 3 times daily at intervals of not less than 4 hours, with a maximum of 3 tablets in 24 hours.

Children under 12 years: Must not be used in children under 12 years of age.

Elderly: There is no need for dosage reduction in the elderly.

Do not exceed the recommended dose.

Do not halve the tablet.

If symptoms do not improve within seven days, consult your doctor.

4.3 Contraindications

Sudomyl is contraindicated for use in children under 12 years of age.

Pseudoephedrine is contraindicated for use in patients:

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

Refer to 'INTERACTIONS' for additional information.

4.4 Special warnings and precautions for use

Pseudoephedrine should be used with caution in patients with:

- hypertension
- hyperthyroidism
- diabetes mellitus
- coronary heart disease
- ischaemic heart disease
- glaucoma
- prostatic hypertrophy
- severe hepatic or renal dysfunction

Caution should be taken when used in conjunction with Cough & Cold Medicines.

Refer to 'INTERACTIONS' for additional information.

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
- methyldopa and β-blockers – may cause an increase in blood pressure

- urinary acidifiers enhance elimination of pseudoephedrine
- urinary alkalinisers decrease elimination of pseudoephedrine

4.6 Fertility, pregnancy and lactation

Use in pregnancy

Category B2: 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

Likely to produce minor or moderate adverse effects on the ability to drive or use machinery.

4.8 Undesirable effects

Adverse effects include:

- cardiovascular stimulation – elevated blood pressure, tachycardia or arrhythmias
- central nervous system (CNS) stimulation – restlessness, insomnia, anxiety, tremors and (rarely) hallucinations
- skin rashes and urinary retention

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

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 adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

In all cases of suspected overdose, immediately call the National Poison Centre in New Zealand on 0800 POISON or 0800 764 766 (24 hours a day).

Symptoms associated with pseudoephedrine overdose may include:

- restlessness
- excitement
- nervousness
- nausea
- vomiting
- abdominal pain
- ataxia
- hallucinations
- convulsions
- tachycardia

In the event of overdose, discontinue medication and seek medical help immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamics/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 central nervous system (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.

5.2 Pharmacokinetic properties

Actions

Pseudoephedrine hydrochloride is a nasal and bronchial decongestant.

Pharmacokinetics

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. Small amounts are distributed into breast milk.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to those included in other sections

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch,
Lactose Monohydrate,
Magnesium Stearate

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

Shelf-life is 36 months from date of manufacture when stored at or below 25^{o}C.

6.4 Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Keep out of reach of children.

6.5 Nature and contents of container

100 tablets in a glass bottle.
500 tablets in a glass bottle (Not currently marketed).
30 tablets in blister packs (Not currently marketed).

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 B2 Controlled Drug

8. SPONSOR

PSM Healthcare Limited, t/a API Consumer Brands
14-16 Norman Spencer Drive
PO Box 76 401
Manukau City
AUCKLAND 2241
Telephone 0508 776746

9. DATE OF FIRST APPROVAL

13/06/1974

10. DATE OF REVISION OF THE TEXT

November 2017

SUMMARY TABLE OF CHANGES

Section changes	Summary of new information
All sections	Reformat as per new datasheet template effective 1/03/2017, and other minor changes.