# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

Noumed Decongestant Tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Noumed Decongestant Tablet contains 60 mg pseudoephedrine hydrochloride.

Pseudoephedrine hydrochloride is a white, crystalline powder or colourless crystals, freely soluble in water and in alcohol, sparingly soluble in methylene chloride. It melts at about 184 °C.

For the full list of excipients, see section 6.1 List of excipients.

## 3. PHARMACEUTICAL FORM

Noumed Decongestant Tablet is a white, round uncoated tablet.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Nasal and sinus decongestant for symptomatic relief of runny noses and sinus congestion.

### 4.2 Dose and method of administration

*Adults & Children 12 years and over*
Take 1 tablet 3 to 4 times a day, when necessary.

Do not exceed 4 tablets per day.

Do not give to children under 12 years.

This product should not be used for more than 7 days except on medical advice.

### 4.3 Contraindications

Noumed Decongestant Tablet is contraindicated for use in patients with the following conditions:

- Known hypersensitivity or idiosyncratic creation to pseudoephedrine (or substances of a similar chemical structure) or to any other ingredient in this medicine (refer to 6.1 List of Excipients).

- Taking monoamine oxidase inhibitors (MAOIs) or who have taken MAOIs within the previous 14 days.
- Uncontrolled hypertension or severe coronary artery disease.

4.4 Special warnings and precautions for use

Noumed Decongestant Tablets should be used with caution in 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*

This product contains pseudoephedrine which 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 elderly*

No data available.

*Paediatric use*

Do not use in children under 12 years of age.

*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 e.g. 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. methyldopa and beta-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

*Effects on fertility*

No data available.

*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.

Noumed Decongestant Tablets should be used in pregnancy only if potential benefits to the patient are weighted against the possibility risk to the foetus.

*Use in Lactation*

Pseudoephedrine is excreted 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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 Undesirable effects

Adverse effects of pseudoephedrine 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
- 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 the table below. The frequencies are provided according to the following convention:

| | |
|---|---|
| Very common | ≥1/10 |
| Common | ≥1/100 and <1/10 |
| Uncommon | ≥1/1000 and <1/100 |
| Rare | ≥1/10,000 and <1/1,000 |
| 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<br>Frequency Category | Adverse Event Preferred Term |
|---|---|
| **Immune System Disorder** | |
| Very rare | Hypersensitivity |
| **Psychiatric Disorder** | |
| Very rare | Anxiety |
| Very rare | Euphoric mood |
| Very rare | Hallucinations |
| Very rare | Hallucination, visual |
| Very rare | Restlessness |
| **Nervous System Disorder** | |
| 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 pustulosis |
| 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 adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

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

Symptoms include convulsions, irritability, palpitations, hypertension and difficulty passing urine.

## 5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

*Mechanism of action*

Pseudoephedrine is a direct- and indirect-acting sympathomimetic agent, with similar actions to ephedrine, but with less cardiovascular or CNS effects.

Pseudoephedrine acts as a decongestant of the mucosa of the nose and sinuses to clear nasal congestion and dry nasal secretions.

*Clinical trials*

No data available.

5.2 Pharmacokinetic properties

*Absorption*

Pseudoephedrine is readily absorbed from the gastrointestinal tract after oral administration. Peak concentrations are reached between 0.5 and 2 hours after administration.

*Distribution*

Distribution into extravascular sites is extensive with the apparent volume of distribution between 2.6 and 5 L/kg.

*Metabolism*

Pseudoephedrine is not substantially metabolised. Less than 1 % of pseudoephedrine is metabolised in the liver, by N-demethylation, to norpseudoephedrine.

*Excretion*

Pseudoephedrine is excreted primarily unchanged in the urine. As pseudoephedrine is a weak base with $pK_a$ of 9.4, the elimination half-life varies from 3 – 6 hours at a urine pH of 5 to 9; 16 hours at pH of 8, with 5 – 8 hours at pH 5.8. At high urine pH (greater than 7), the drug is extensively reabsorbed in the renal tubules and the rate of excretion is therefore dependent on pH and urine flow rate. This does not appear to be the case at low urine pH.

5.3 Preclinical safety data

*Genotoxicity*

No data available.

*Carcinogenicity*

No data available.

## 6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Calcium hydrogen phosphate dihydrate
- Microcrystalline cellulose
- Magnesium stearate

6.2 Incompatibilities

No data available.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30 °C. Keep out of reach of children.

6.5 Nature and contents of container

The tablets are presented in PVC/PVDC/Aluminium blister packs which are enclosed in a carton. Each blister pack contains 12 tablets.

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements by taking to your local pharmacy.

7. MEDICINE SCHEDULE Controlled

Drug C3.

8. SPONSOR

Noumed Pharmaceuticals Limited

Auckland, New Zealand

Freephone 0800 527 545

9. DATE OF FIRST APPROVAL

TBC

10. DATE OF REVISION OF THE TEXT

26 March 2024

SUMMARY TABLE OF CHANGES

| Section changes | Summary of new information |
|---|---|
| All | New |