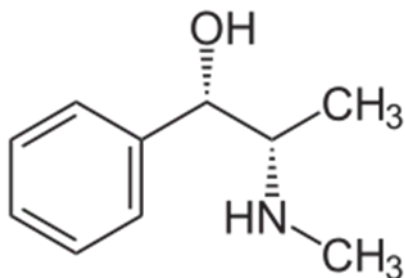


TRUST SINUS & NASAL DECONGESTANT TABLETS
AUST R: TBA

i) Name of the medicine

Pseudoephedrine hydrochloride



Molecular formula (C₁₀H₁₅NO, HCl)

Molecular weight: 201.7

CAS Registry number: 345-78-8

ii) Description

Tablets: Active ingredient is Pseudoephedrine hydrochloride 60mg.

Inactive ingredients are magnesium stearate, cellulose – microcrystalline, and calcium hydrogen phosphate.

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.

iii) Pharmacology

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

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

Pharmacokinetics:

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 5L/kg.

Metabolism

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

Excretion

Product Information - Trust Sinus & Nasal Decongestant

As pseudoephedrine is a weak base with pKa 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.

vi) Clinical Trials

This information is not available.

v) Indications

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

vi) Contraindications

Known hypersensitivity to pseudoephedrine or to any other ingredient in the product (refer to composition).

Patients receiving monoamine oxidase (MAO) inhibitor antidepressants and within 14 days of ceasing treatment with a MAO inhibitor.

Patients with severe hypertension or severe coronary artery disease.

Children under 12 years.

vii) Precautions

Trust Sinus & Nasal Decongestant Tablets should be administered with caution to patients with hypertension, hyperthyroidism, heart disease, patients with diabetes mellitus, patients with prostatic enlargement, elevated intraocular pressure and bladder dysfunction.

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

Use in pregnancy. (Category B2). Animal reproduction studies have not been conducted with pseudoephedrine. It is also not known whether pseudoephedrine can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. Trust Sinus & Nasal Decongestant Tablets should be given to a pregnant woman only if clearly needed.

Australian categorisation definition of Category B2 drugs which have 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 adequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

Use in lactation. Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast fed infants is not known. Use of pseudoephedrine while breastfeeding is not recommended.

viii) Interactions with other medicines

The effects of pseudoephedrine may be enhanced by acetazolamide, disodium hydrogen citrate, sodium acid citrotartrate and sodium bicarbonate. Acetazolamide may reduce the

Product Information - Trust Sinus & Nasal Decongestant

glomerular filtration rate in the kidney, and decrease the rate of elimination of pseudoephedrine. Citrates and sodium bicarbonate could increase urinary pH, and decrease the rate of elimination of pseudoephedrine.

Concurrent use of pseudoephedrine with monoamine oxidase (MAO) inhibitor antidepressants may cause severe hypertension and headaches. Pseudoephedrine should not be taken within 14 days of ceasing treatment with a MAO inhibitor (see “Contraindications”).

Concomitant use of pseudoephedrine and other sympathomimetic agents, may lead to an increase in blood pressure and increase the potential for other side effects.

Administration with tricyclic antidepressants may increase blood pressure or increase the risk of arrhythmias.

Administration with digitalis glycosides, quinidine or levodopa may increase the risk of arrhythmias.

The antibacterial agent, furazolidone, is known to cause a progressive inhibition of monoamine oxidase. Although there are no reports of a hypertensive crisis caused by the concurrent administration of pseudoephedrine and furazolidone, they should not be taken together.

Pseudoephedrine may inhibit the effects of antihypertensive medication, including methyl dopa or beta adrenergic blocking agents.

Administration with other CNS stimulants may lead to increased CNS stimulation.

ix) Adverse effects

Pseudoephedrine may cause insomnia, urinary retention or dose-dependent CNS excitation. Rarely, sleep disturbances and hallucinations have been reported. Other symptoms may occur, such as nervousness, tremor, vertigo, headache, tachycardia, palpitations, sweating or flushing, anxiety, restlessness, dry mouth, anorexia and tension.

x) Dosage and Administration

Dosage and Administration:

Trust Sinus & Nasal Decongestant tablets (60mg)

Adults and children over 12 years: 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.

xi) Overdosage

Product Information - Trust Sinus & Nasal Decongestant

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

Treatment. In case of overdose, or for further information, contact the Poisons Information Centre on 13 11 26.

xii) Presentation and storage conditions

Trust Sinus & Nasal Decongestant tablets 60mg are white round-shaped tablets, available in a blister pack of 12s.

Store below 30°C

xiii) Name and address of Sponsor

Pharmacor Pty Ltd
Suite 401, 7 Oaks Avenue
DEE WHY NSW 2099
AUSTRALIA

xiv) Poison schedule of the medicine

Trust Sinus and Nasal Decongestant tablets are S3

xv) Date of the first inclusion on the Australian Register of Therapeutic Goods

TBA

xvi) Date of most recent amendment

18th November 2014