

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Decongestant Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredient</u>	<u>per tablet</u>
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Pseudoephedrine hydrochloride	60 mg
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3 PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of nasal and sinus congestion without causing drowsiness.

4.2 Posology and method of administration

Adults and children over 12 years: One tablet. The dose may be taken if necessary, up to four times daily at intervals of not less than 4 hours.

Children under 12 years: Not recommended.

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

For oral administration.

4.3 Contraindications

Hypersensitivity to any of the ingredients. Avoid in patients with cardiovascular disease, severe renal impairment, diabetes mellitus, closed angle glaucoma, hyperthyroidism, prostatic enlargement and phaeochromocytoma.

4.4 Special warnings and precautions for use

If symptoms do not go away talk to your doctor.

Keep all medicines out of the reach of children.

Warning: Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

Should not be given to patients being treated with monoamine oxidase inhibitors or within 14 days of stopping such treatment. May enhance the effects of anticholinergic drugs such as tricyclic antidepressants. May increase the possibility of arrhythmias in digitised patients.

4.6 Pregnancy and lactation

The safety of decongestant tablets during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to pseudoephedrine, the use of the product during pregnancy should be avoided. The amounts of pseudoephedrine secreted into breast milk are considered to be too small to be harmful.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Adverse effects may include anxiety, restlessness, tremor, insomnia, tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting and headache and occasionally urinary retention and skin rashes. Hallucinations have been reported rarely, particularly in children.

4.9 Overdose

Symptoms of overdosage include irritability, restlessness, palpitations, hypertension, difficulty in micturition, nausea, vomiting, thirst and convulsions. In severe overdosage gastric lavage and aspiration should be

performed. Symptomatic and supportive measures should be undertaken, particularly with regard to cardiovascular and respiratory systems. Convulsions should be controlled with intravenous diazepam. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta blocker may be required to control cardiac arrhythmias.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pseudoephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors.

It has alpha and beta adrenergic activity and some stimulant effect on the central nervous system. The sympathomimetic effect of pseudoephedrine produces vasoconstriction which in turn relieves nasal congestion.

5.2 Pharmacokinetic properties

Pseudoephedrine is readily absorbed from the gastrointestinal tract and is largely excreted in the urine unchanged. It has an elimination half-life of 5 to 8 hours but its urinary elimination and hence half-life, is pH dependent. Pseudoephedrine is rapidly distributed throughout the body, its volume of distribution being 2 to 3L/kg bodyweight.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Explotab

Maize starch pdr

Microcrystalline cellulose

Pregelised maize starch

Stearic acid.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

A card carton containing a blister push-through pack consisting of a PVC/PVDC blister heat sealed to a hard temper aluminium foil.

Pack size: 12

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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January 2007

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18/06/2008