

SUMMARY OF PRODUCT CHARACTERISTICS

1. **NAME OF THE MEDICINAL PRODUCT**

Galpseud Tablets

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active Ingredient:

Pseudoephedrine hydrochloride 60.0mg (Per Tablet).

For full list of excipients, see section 6.1.

3. **PHARMACEUTICAL FORM**

Tablets.

Round, curved white tablets embossed with “60” on one side.

4. **CLINICAL PARTICULARS**

4.1 **Therapeutic Indications**

Indicated for the relief of nasal, sinus and upper respiratory congestion.

4.2 **Posology and method of administration**

For oral administration.

Adults and children over 12 years:

One tablet four times daily.

Elderly:

Adult dose is appropriate.

4.3 **Contraindications**

This product should not be used in patients hypersensitive to pseudoephedrine or any of the other ingredients.

Patients receiving monoamine oxidase inhibitors or who have received these agents in the last two weeks. Patients using other sympathomimetic decongestants or beta-blockers. (See Section 4.5).

Patients with cardiovascular disease including ischaemic heart disease, occlusive vascular disease and hypertension.

Children under 12 years of age.

Patients with:

- Severe renal impairment
- Pheochromocytoma
- Diabetes
- Hyperthyroidism
- Closed angle glaucoma
- Severe hypertension or uncontrolled hypertension
- Severe acute or chronic kidney disease/renal failure.

4.4 Special warnings and precautions for use

Caution should be used when prescribing pseudoephedrine for patients with prostatic enlargement or bladder dysfunction.

Also use with caution in patients with severe hepatic impairment, or with mild to moderate renal impairment.

If any of the following occur, the product should be stopped

- Hallucinations
- Restlessness
- Sleep disturbances.

Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Do not exceed the stated dose.

Keep out of the sight and reach of children.

Severe Skin reactions

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as

pyrexia, erythema, or many small pustules are observed, administration of Galpseud Tablets should be discontinued and appropriate measures taken if needed.

Ischaemic colitis

Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Posterior reversible encephalography syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing products (see section 4.8). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see section 4.3).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be exercised with patients receiving other sympathomimetic agents (e.g. avoid use with apraclonidine), appetite suppressants or other amphetamine-like psychostimulants, as there is a risk of hypertension.

Pseudoephedrine may antagonise the effects of antihypertensive agents, such as adrenergic neurone blockers, and severe hypertension may occur in patients receiving beta-blockers. Hypertensive crisis may occur if pseudoephedrine is co-administered with MAOIs. Concomitant use of pseudoephedrine should be avoided with MAOIs including rasagiline and selegiline, or RIMAs such as moclobemide.

There may be increased risk of arrhythmias if pseudoephedrine is given to patients receiving cardiac glycosides, quinidine, volatile anaesthetics such as cyclopropane, or halothane, or anticholinergic drugs such as tricyclic antidepressants. Pseudoephedrine also increases the risk of ergotism if used with ergot alkaloids, ergotamine and methysergide.

The effects of pseudoephedrine may be antagonised by antipsychotics and its absorption rate may be reduced by kaolin.

The effects of pseudoephedrine may be increased by doxapram and oxytocin (as there is a risk of hypertension) and its absorption may be increased by aluminium hydroxide.

The antibacterial agent furazolidone is known to cause progressive inhibition of monoamine oxidase (a metabolite of furazolidone is a MAOI). Although there have been no reports of hypertensive crisis, it may not be administered concurrently with pseudoephedrine.

4.6 Fertility, pregnancy and lactation

There are limited data from the use of pseudoephedrine in pregnant women. It is advised that pseudoephedrine should be avoided during pregnancy, particularly during the first trimester, as defective closure of the abdominal wall (gastroschisis) has been reported very rarely in new-borns after first trimester exposure.

Pseudoephedrine has been detected in human milk with a small percentage of the total maternal dose potentially administered to the suckling infant. The use of pseudoephedrine should be avoided during breast feeding as lactation may be suppressed, and irritability and disturbed sleep have been reported in breast fed infants.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The following side effects may be associated with the use of pseudoephedrine: (frequencies not known: cannot be estimated from the available data).

Immune system disorders:

Hypersensitivity reactions – cross-sensitivity may occur with other sympathomimetics.

Psychiatric disorders:

Hallucinations (particularly in children), insomnia, sleep disturbances, anxiety, restlessness, irritability, excitability, psychotic disorder has occurred rarely following misuse of pseudoephedrine.

Nervous system disorders:

Headache, tremor, dry mouth.

Eye disorders:

Angle-closure glaucoma.

Cardiac disorders:

Tachycardia, palpitations, arrhythmia.

Vascular disorders:

Hypertension, impaired circulation to the extremities.

Gastrointestinal disorders:

Nausea, vomiting, ischaemic colitis.

Skin and subcutaneous tissue disorders:

Fixed drug eruption in the form of erythematous nodular patches, rash. Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP).

Renal and urinary disorders:

Urinary retention.

Posterior reversible encephalopathy syndrome:

See Section 4.4.

Reversible cerebral vasoconstriction syndrome:

See Section 4.4.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

The symptoms of overdose include irritability, nervousness, tremor, cardiac arrhythmias, palpitations, tachycardia, convulsions, urinary retention and hypertension, restlessness, dry mouth, anxiety, insomnia, nausea, vomiting and possible tolerance to pseudoephedrine.

Overdose should be treated by general supportive measures. Respiratory and circulatory function should be maintained by supportive measures. Catheterisation of the bladder may be required.

The benefit of gastric decontamination is uncertain. Consider activated charcoal (charcoal dose: 50 g for adults; 1g/kg for children). Optimal effects are within 1 hour of ingestion of more than a toxic dose. Volunteer studies suggest that there is reduced absorption within 2 hours and efficacy declines thereafter. Alternatively consider gastric lavage in adults within 1 hour of a potentially life-threatening overdose. Monitor pulse, blood pressure and cardiac rhythm. Treat any hypertension or convulsions as necessary.

Asymptomatic patients should be observed for 4 hours or 8 hours if a slow release product has been taken.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Nasal Decongestants for Systemic Use, Sympathomimetics. ATC code: R01B A02.

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory decongestant. Pseudoephedrine is

substantially less potent than ephedrine in producing both tachycardia and elevation in systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.

5.2 Pharmacokinetic properties

Pseudophedrine hydrochloride is readily and completely absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance that are additional to the prescriber, which are additional to those already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Microcrystalline cellulose
Magnesium stearate

6.2 Incompatibilities

None stated.

6.3 Shelf life

Three years from the date of manufacture.

6.4 Special precautions for storage

Store in a cool dry place.

Protect from light.

6.5 Nature and contents of container

White opaque PVC blister 250 microns thick backed by hard temper aluminium foil 20 microns thick.

Pack sizes: 24 tablets.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Thornton and Ross
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0351

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/10/2024

10 DATE OF REVISION OF THE TEXT

09/10/2024