Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Galpseud 60mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: Pseudoephedrine Hydrochloride 60.0 mg

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

Round, convex, white tablets embossed with 'Gal' on one side and '60' on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a nasal decongestant in the symptomatic relief of conditions such as the common cold and influenza and the short term relief of allergic and vasomotor rhinitis.

4.2 Posology and method of adminstration

For oral administration.

Adults and children over 12 years:
The usual dose is one tablet (60mg) three times daily.

4.3 Contraindications

Use in patients hypersensitive to the active ingredient.

Use in patients who are receiving monoamine oxidase inhibitors or who have received these within the previous 14 days.

Use in patients with severe hypertension or severe coronary artery disease.

Use in patients with severe renal impairment.

Use concurrently with furazolidone.

4.4 Special warnings and precautions for use

The product should be used only with caution in patients with renal impairment, prostatic hypertrophy, thyrotoxicosis, glaucoma or urinary retention.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose

malabsorption should not take this medicine.

Use with caution in diabetic patients as the product may cause an increase in blood sugar level.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use with sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants, or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.
There may be an increased risk of arrhythmias if pseudoephedrine is given to patients receiving cardiac glycosides or tricyclic antidepressants.

Pseudoephedrine may reduce the hypotensive effect of antihypertensives with sympathomimetic activity.

Caution should be exercised during use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents as they may provoke or worsen ventricular arrhythmias.

4.6 Pregnancy and lactation

This product should not be used in pregnancy unless considered essential by the physician.

Pseudoephedrine is excreted in breast milk in small amounts.

4.7 Effects on ability to drive and use machines

Does not affect the ability to drive or operate machinery.

4.8 Undesirable effects

Side effects include symptoms of central nervous system excitation such as restlessness. Tachycardia, sleep disturbances, anxiety, tremor, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting, headache and more rarely hallucinations, skin rash and urinary retention have also been reported.

There have been rare cases of psychosis following misuse of pseudoephedrine.

4.9 Overdose

The symptoms of overdose include irritability, nervousness, tremor, palpitations, convulsions, restlessness, difficulty in micturition, nausea, vomiting, tachycardia, cardiac arrhythmias, urinary retention and hypertension.

Overdose should be treated by general supportive measures. In the event of gross overdose, the stomach should be emptied using airway protective gastric lavage. Respiratory and circulatory function should be maintained by supportive measures. Convulsions should be controlled using anti-convulsant therapy. Catheterisation of the bladder may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

R01B A02 – Nasal decongestants for systemic use, sympathomimetics.

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

Pseudoephedrine 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

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene tablet containers with polyethylene snap-close caps (100 or 500 tablets) and/or opaque PVC blisters (250 micron) backed by hard temper aluminium foil (20 micron) (18 tablets).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
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HD7 5QH
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8 MARKETING AUTHORISATION NUMBER

PA 610/14/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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