SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galpseud Plus Linctus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients:
Per 5ml Dose:

Pseudoephedrine hydrochloride	30mg
Chlorphenamine maleate	2.0mg

Excipient(s) with known effect:
Per 5ml Dose:

Ethanol (96%)	80mg
Sodium parahydroxybenzoates (E215, E217, E219)	7.5mg
Amaranth (E123)	0.25mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of allergic rhinitis.

4.2 Posology and method of administration

For oral administration.

Adults:
Two 5ml spoonfuls three times daily.

Children:
Under 2 years: Not recommended.
2 – 6 years: 2.5ml three times daily.
6 – 12 years: 5ml three times daily.

Not more than 3 doses should be given in any 24 hours.

4.3 Contraindications

Contra-indicated in patients with a known hypersensitivity to pseudoephedrine hydrochloride or chlorphenamine maleate or any of the other ingredients. Contra-indicated in epileptics because of the antihistamine content and in patients currently taking or within 2 weeks of stopping monoamine oxidase inhibitors. Contra-indicated in severe hypertension or uncontrolled hypertension, or in patients receiving antihypertensive therapy.
Contra-indicated in severe acute or chronic kidney disease/renal failure.
Not recommended for children under 2 years.

4.4 Special warnings and precautions for use

Asthmatics should consult a medical practitioner before using this product.

Caution should be exercised in patients with renal impairment, urinary retention, diabetes, hyperthyroidism, glaucoma, hepatic impairment or cardiovascular disease and those taking other sympathomimetic agents, such as decongestants, amphetamine-like psychostimulants and appetite suppressants.

The effects of single dose of Galpseud Plus on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. As with other sympathomimetic agents, caution should be exercised in patients with prostatic enlargement or bladder dysfunction.

In severe hepatic or renal dysfunction, a single dose of Galpseud Plus should be given, and the patient's response used as a guide to the dosage requirement for further administration.

If symptoms persist consult your doctor.

Do not exceed the stated dose.

Do not take with other cough and cold medicines.

Consult a pharmacist or other healthcare professional before use in children under 6 years.

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 this product 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.

Ischaemic optic neuropathy

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

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.

Excipient warnings:

This medicine contains sodium parahydroxybenzoates (E215,E217,E219) and amaranth (E123). May cause allergic reactions (possibly delayed).

This medicine contains 154mg of alcohol (ethanol) in each 10ml dose which is equivalent to 1.9%v/v. The amount in 10ml of this medicine is equivalent to less than 4ml of beer or 2ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1mmol sodium (23mg) per 2.5ml dose, that is to say essentially “sodium-free’’.

4.5 Interaction with other medicinal products and other forms of interaction

The antibacterial agent furazolidone is known to cause progressive inhibition of monoamine oxidase and although there are no reports of a hypertentive crisis having occurred, it should not be administered concurrently with Galpseud Plus.

There may be an increased risk of arrythmias if pseudoephedrine is given to patients receiving cardiac glycosides or tricyclic antidepressants. Pseudoephedrine may reduce the hypotensive effect of antihypertensives with sympathomimetic activity. Concurrent use of pseudoephedrine with monoamine oxidase inhibitors may cause a hypertensive crisis. Chlorphenamine may enhance the sedative effects of CNS

depressants, including alcohol, barbiturates, hypnotics, anxiolytics, sedatives and anti-psychotics. As chlorphenamine possesses anticholinergic activity the effects of some anticholinergics may be potentiated.

4.6 Pregnancy and lactation

Not to be used during pregnancy and lactation without prior consultant with a medical practitioner. Pseudoephedrine is excreted in breast milk in small amounts.

4.7 Effects on ability to drive and use machines

May cause drowsiness, if affected do not drive or operate machinery. The drowsiness may be potentiated by alcohol or other central sedatives.

4.8 Undesirable effects

Pseudoephedrine may cause anxiety, tremor, cardiac arrhythmias, palpitations, tachycardia, hypertension, nausea, vomiting, headache and may occasionally cause insomnia and urinary retention in men. Rarely sleep disturbance and hallucinations have been reported.
There have been rare cases of psychosis following misuse of pseudoephedrine.

Chlorphenamine may cause drowsiness, nausea, vomiting, headaches, blurred vision, anorexia and dryness of the mouth.

The administration of antihistamines has also been associated with rash, angioedema, convulsions, parasthesias, dizziness and constipation.

Eye disorders
Frequency unknown: Ischaemic optic neuropathy

Skin and subcutaneous tissue disorders
Frequency unknown: Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP)

Gastrointestinal disorders
Frequency unknown: Ischaemic colitis

Posterior reversible encephalography 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 or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of overdose may include restlessness, drowsiness, tetany, hallucinations, excitement, ataxia, convulsions, fever, nausea, vomiting, difficulty in micturition, flushing, palpitations, tachycardia, cardiac arrhythmias and respiratory difficulties. Overdose should be treated by general symptomatic and supportive means. In the event of gross overdose the stomach may be emptied by airways protective gastric lavage. If consciousness is impaired or if respiration or circulatory difficulties are evident, appropriate supportive measures should be taken to maintain a patient's airway and to stabilise cardiovascular function. Convulsions should be controlled by immediate appropriate measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract 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.
Chlorphenamine is one of the most potent anti-histamines. It is useful in the control of symptoms which are allergic in origin. It helps to provide relief from nasal stuffiness and watering of the eyes.

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.

Chlorphenamine maleate is readily absorbed from the gastro-intestinal tract. It is extensively metabolised in the liver and excreted in the urine.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate (E330)
Sodium hydroxybenzoates (E215, E217, E219)
Ethanol (96%)
Amaranth (E123)
Carmellose sodium (E466)
Saccharin sodium
Levomenthol
Condensed milk flavour (F12516)
Orange flavour (17.40.7040)
Glycerol (E422)
Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

Two years from the date of manufacture.

6.4 Special precautions for storage

Protect from light.
Store below 25°C.

6.5 Nature and contents of container

Amber glass bottle with a 28mm tamper evident child resistant closure with a low density polyethylene plug
Pack size: 500ml.

6.6 Instructions for use and handling

None stated.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.

Linthwaite

Huddersfield

HD7 5QH

United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00240/0108

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

8 July 2002

10 DATE OF REVISION OF THE TEXT

17/04/2024