SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Galpseud Linctus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients:
Pseudoephedrine hydrochloride 30.0mg (per 5ml dose)

Excipient(s) with known effect:
Each 5ml dose contains:

Sodium hydroxybenzoates (E215, E217 & E219)	7.5mg
Alcohol (Ethanol) 96%	76.8mg
Amaranth (E123)	0.1mg
Sunset yellow FCF (E110)	0.5mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral liquid.

A deep orange coloured liquid.

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:
Two 5ml spoonfuls three times daily.

Children:
6-12 years: 5ml three or four times daily.

Elderly:
Adult dose is appropriate.

4.3 Contraindications

Galpseud Linctus 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 6 years of age.

Patients with:

- Severe renal impairment
- Phaeochromocytoma
- 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 in prescribing Galpseud Linctus 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, Galpseud Linctus should be stopped

- Hallucinations
- Restlessness
- Sleep disturbances.
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Excipient warnings:
This medicine contains Amaranth (E123), Sunset Yellow (E110) and Sodium hydroxybenzoates (E215, E217 & E219) which may cause allergic reactions (possibly delayed).

This medicine contains 76.8mg of ethanol (alcohol) in each 5ml dose which is equivalent to 1.9% v/v. The amount of ethanol in 5ml of this medicine is equivalent to less than 2ml of beer and 1ml 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 5ml dose, that is to say essentially 'sodium-free'.

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 Linctus 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.

Do not exceed the stated dose.
Keep out of the sight and reach of children.

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 amphetamine-like psychostimulants, as there is a risk of hypertension.

Pseudoephedrine may antagonise the pressor 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 an 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 Galpseud Linctus.

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.
Ischaemic optic neuropathy

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 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.
By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

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

5.2 Pharmacokinetic properties

Pseudoephedrine hydrochloride is readily and completely absorbed from the gasto-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 to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate (E330)

Sodium hydroxybenzoates (E215, E217 & E219)

Alcohol (Ethanol) 96%

Amaranth (E123)

Sunset yellow FCF (E110)

Carmellose sodium (E466)

Saccharin sodium (E954)

Menthol

Condensed milk flavour (F12516)

Orange flavour (17.40.7040)

Glycerol (E422)

Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

Amber HDPE 2 litre Winchester with a polypropylene cap.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd
Linthwaite
Huddersfield
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0350

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/10/2024

10 DATE OF REVISION OF THE TEXT

09/10/2024