SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

TIPTIPOT AFALPI

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients:
PSEUDOEPHEDRINE (AS HYDROCHLORIDE) 15 MG/ML

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Drops.

A clear, yellowish liquid with strawberry smell.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of nasal congestion, to relief eustachian tube congestion..

4.2 Posology and method of administration

For oral administration.

The generally accepted dosage is:
For children 6-12 years old: one drop per kg body weight per dose, up to 4 doses per 24 hours (a maximum of 30 drops per dose).
For children 1 to 6 years old, the medicine should be dispensed with a doctor's prescription only.

4.3 Contraindications

- Hypersensitivity to pseudoephedrine or to any of the excipients listed in section 6.1.
- 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 1 year of age.

- Patients with:
  - Severe acute or chronic kidney disease/renal failure
  - severe hypertension or uncontrolled hypertension
  - Phaeochromocytoma
  - Diabetes
  - Hyperthyroidism
  - Closed angle glaucoma.

4.4 Special warnings and precautions for use

Caution should be used in prescribing Tiptipot Afalpi 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, Tiptipot Afalpi should be stopped
- Hallucinations
- Restlessness
- Sleep disturbances.

Excipients with known effect:
Tiptipot Afalpi contains Sorbitol. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

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 Tiptipot Afalpi 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 encephalopathy 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 Tiptipot Afalpi.

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.
Posterior reversible encephalopathy syndrome (PRES) (see section 4.4)
Reversible cerebral vasoconstriction syndrome (RCVS) (see section 4.4)

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.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/

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

Sorbitol Solution 70%, Sodium Citrate, Citric acid, Strawberry cream flavor, Saccharin Sodium, Sodium Benzoate, Disodium Edetate, purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening of the bottle: 6 months

6.4 Special precautions for storage

Store below 25°C in original package.

6.5 Special precautions for disposal

None stated.

7 MANUFACTURER AND MARKETING AUTHORISATION HOLDER

CTS CHEMICAL INDUSTRIES LTD
POB 385,KIRYAT-MALACHI,ISRAEL

8 MARKETING AUTHORISATION NUMBER(S)

121-43-30172-00

9 DATE OF REVISION OF THE TEXT

Revised in 03/2024 according to the MOHs guidelines