PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Tiptipot Afalpi

Oral drops

The active ingredient and its concentration
Pseudoephedrine (as hydrochloride)
15 mg/ml
Each drop contains 1.00 mg of pseudoephedrine.
Inactive ingredients and allergens in the preparation - see section 6 and the "Important information about some ingredients of the medicine" section.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
The medicine is not intended for babies under 1 year of age.
For children 1 to 6 years old, the medicine is dispensed with a doctor's prescription only.
Take the product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you have further questions.
Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve, or if fever develops after 7 days.

1. What is the medicine intended for?

The medicine is intended for relief of nasal congestion and middle ear congestion.
Therapeutic class: the active ingredient belongs to the class of sympathomimetic agents.
The active ingredient pseudoephedrine is a decongestant which acts to constrict blood vessels and to reduce swelling and mucous production, and thus relieves congestion.

2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains.
- You are currently treated with medicines of the monoamine oxidase inhibitors group (for depression) or you have stopped using such medicines less than 14 days ago.
- You are suffering from a severe problem in your kidneys, heart disease, circulation problems, hypertension, diabetes, overactive thyroid gland, glaucoma, pheochromocytoma (a tumor in the adrenal gland).
- You are pregnant or breastfeeding.
- You are taking medicines of the beta receptor-blockers group or other medicines for treatment of nasal congestion (including spray).
- The patient is under 1 year of age.

❗ Special warnings regarding the use of the medicine:

- **Before treatment with Tiptipot Afalpi, inform the doctor if:**
  - You are suffering from dysfunction of the prostate or the bladder, a moderate kidney disease, or a severe liver disease.
- If you develop disseminated erythema with fever and pustulosis, you should stop using the medicine and contact a doctor immediately. See section 4 - Side effects.
- Sudden abdominal pain or rectal bleeding may occur with Tiptipot Afalpi, due to an inflammation of the colon (ischaemic colitis). If you develop these gastrointestinal symptoms, you should stop using the medicine and contact a doctor immediately. See section 4 - Side effects.
- Reduction of blood flow to the optic nerve may occur with this medicine. If you develop sudden loss of vision, you should stop using the medicine and contact a doctor immediately. See section 4 - Side effects.
- You should tell the doctor that you are taking this medicine if you arrive at a hospital's emergency room, since the medicine may interfere with other medicines or anesthetics.

❗ Drug interactions
Do not use together with:

- Medicines of the monoamine oxidase inhibitors group (for depression) or within 14 days of stopping treatment with such medicines.
- Medicines of the beta receptor-blockers group or other medicines for treatment of nasal congestion (including spray).

❗ If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Medicines that stimulate the central nervous system (e.g. amphetamines).
- Appetite suppressants.
- Antidepressants.
- Medicines for lowering blood pressure.
- Medicines for treatment of heart diseases such as: beta-blockers, digoxin, quinidine, digitoxin.
- Cough and cold medicines.
- Medicines for mental diseases.
- Medicines for treatment of Parkinson's disease, e.g. selegiline, rasagiline.
- Medicines for treatment of migraines, e.g. ergotamine, methysergide.
- Medicines for treatment of glaucoma, e.g. apraclonidine.
- Antacids, e.g. aluminum hydroxide, kaolin.
- Antibiotics, e.g. furazolidone.

❗ Pregnancy, breastfeeding and fertility:
The medicine must not be used if you are pregnant or breastfeeding.

❗ Important information about some ingredients of the medicine
This medicine contains 280 mg of sorbitol in each 1 ml, which is equivalent to 18.67 mg of sorbitol in each drop. Sorbitol is a source of fructose. If there is a known intolerance to certain sugars, or a diagnosis of hereditary fructose intolerance, consult with your doctor before taking this medicine. This medicine contains 1 mg of sodium benzoate in each 1 ml, which is equivalent to 0.07 mg of sodium benzoate in each drop. This medicine contains less than 23 mg of sodium per 1 ml, and is therefore considered sodium-free.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
This medicine is not intended for children under 1 year of age.
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.

Do not exceed the recommended dose
Attention:
Be sure to measure the dose with the dropper.

Method of administration:

1. Do not shake the medicine before use; shaking makes it difficult for the drops to leave the dropper.
2. The original dropper is calibrated to release a measured and accurate amount with each use. Do not replace the original dropper with another.
3. Open the stopper by simultaneously pushing it downwards and turning it counter-clockwise (see figure 1).
4. Hold the bottle vertically over the spoon and wait for the drops to come out (see figure 2).
5. If no drops come out, tap lightly on the bottle's bottom (see figure 3).
6. Count the drops precisely.
7. Pour the measured content of the spoon into the baby's mouth.

Do not pour the medicine directly from the bottle into the baby's mouth!
Wipe the bottle's top (the dropper). Be sure to put the stopper on tightly immediately after you finish using the medicine in order to prevent the dropper from clogging.
If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Tiptipot Afalpi may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
You should stop using the medicine and contact a doctor immediately if the following symptoms occur:

- An allergic reaction, signs may include: breathing difficulties, fever, swelling of the mouth, lips or skin, severe skin rash, itching, abdominal pain.
- A sudden fever, reddening of the skin, or appearance of many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis – AGEP), which may occur during the first two days of treatment with the medicine. See section 2 - Special warnings regarding the use of the medicine.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis).
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy).

Additional side effects:
Hallucinations, restlessness, insomnia, nausea, vomiting, headache, skin rash, blisters and red skin patches, glaucoma, anxiety, nervousness, difficulty urinating, fast or irregular heartbeat, palpitations, high blood pressure, tremor, dry mouth, poor circulation (cold hands or feet), mental illnesses (rare).
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.

- Store at a temperature lower than 25°C.
- Store in the original package.
- Once the bottle is opened for the first time, the medicine may be used for 2 months.

6. Additional information:

- In addition to the active ingredient the medicine also contains:

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

- What does the medicine look like and what are the contents of the package: Tiptipot Afalpi is a clear, yellowish liquid with strawberry smell. Each package contains one 15 ml glass bottle.
- License holder/manufacturer and the address: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.
- This leaflet was revised in 03/2022 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1214330172

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