



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

The medicine is dispensed without a doctor's prescription.

Tussophedrine NF Syrup

Active ingredients: each 5 ml of syrup contains:

Potassium guaiacolsulphonate 120 mg
Sodium benzoate 20 mg
Ephedrine HCl 6 mg
Dextromethorphan hydrobromide 5 mg

For inactive ingredients in the preparation - see section 6: "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is not intended for children and infants under 1 year of age.

You must use/take it correctly. Consult the pharmacist if you need more information. Refer to a doctor if the symptoms get worse or if they do not improve after 7 days.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is intended to relieve cough.

Therapeutic group

Ephedrine is a sympathomimetic.
Dextromethorphan hydrobromide is a cough suppressant.
Potassium guaiacolsulphonate is an expectorant.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- during an asthma attack or respiratory depression.
- if you are pregnant or breastfeeding.
- if you are currently taking a monoamine oxidase inhibitor (for depression) or you have stopped taking it within the last 14 days.
- if you are taking a SSRI (selective serotonin reuptake inhibitor, such as fluoxetine).
- if you are suffering from problems with liver function.
- in infants under 1 year of age.

Special warnings regarding use of the medicine

- Do not use this medicine often or for a prolonged period without consulting a doctor.
- If you are sensitive to any food or medicine, you must inform the doctor before taking the medicine.

Do not use this medicine without consulting a doctor before commencing treatment:

- if you are suffering, or have suffered in the past, from impaired function of: the respiratory system (such as asthma), the heart and/or blood vessels, the eyes (such as glaucoma), the kidney/urinary tract, the thyroid gland, the prostate.
- if you are suffering or have suffered in the past, from allergy (especially allergy to medicines), from diabetes.
- in case of prolonged cough caused by smoking or any problem involving the respiratory system, such as: asthma, emphysema, COPD (chronic obstructive pulmonary disease), or cough accompanied by a lot of phlegm (see also section "Do not use the medicine").

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

- medicines that affect the central nervous system (such as: sedatives, hypnotics, medicines for Parkinson's, epilepsy, allergy, surgical anesthetics and narcotic analgesics).
- antidepressants of the monoamine oxidase inhibitor or SSRI type (see also section "Do not use the medicine").
- antihypertensives and heart medicines (such as beta blockers).
- medicines for migraine.
- cold-treating medicines and/or medicines for allergy.

Use of the medicine and alcohol consumption

Do not drink wine or alcoholic beverages during treatment with this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, do not use the medicine.

Driving and operating machinery

Using the medicine can impair alertness and/or vision. Therefore, you must exercise caution when driving a car, operating dangerous machinery, and during any activity that requires alertness. Children must be cautioned against riding a bicycle or playing near the road and the like.

Smoking

If you smoke - report this to the doctor before starting treatment with this medicine.

Important information regarding some of the ingredients of the medicine:

This medicine contains sugar and sodium.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about how to use this medicine.

The usual dosage is generally:

Adults and children over 12 years of age:

10 ml x 3 times a day and 10 ml in the evening before bedtime.

Children 6-12 years of age: 5 ml x 3 times a day, half an hour before meals.

Children from 1 year to 6 years of age: dosage will be determined according to the doctor's instructions.

Do not exceed the recommended dose.

This medicine is not intended for children and infants under 1 year of age.

Refer to a doctor if your condition does not improve within 7 days.

Method of administration:

1. With liquid medicines, you must use the measuring spoon, syringe or dropper designated for measuring the correct amount of medicine. Consult a pharmacist if a spoon or other measuring device has not been enclosed. Do not use a household teaspoon to measure the amount of the medicine. Household teaspoons vary in their sizes and you may not get the correct amount of medicine. Rinse the measuring spoon after use.
2. Child-proof caps have significantly reduced the number of cases of medicine-induced poisoning annually. However, if you find it difficult to open the container, you can ask the pharmacist to remove the safety mechanism of the cap and make it a regular, easy to open cap.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tussophedrine NF may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor if the following effects develop:

- Sudden signs of allergy, such as: rash, itching, fever, swelling of the throat, face, lips, eyelids, tongue and/or other parts of the body, shortness of breath/difficulty breathing, anaphylactic shock.
- Sensation of cold in the tips of hands or legs, nausea, decrease/increase in heart rate.

Additional side effects:

Common side effects:

Dizziness, stomach upset, drowsiness.

Side effects of unknown frequency:

Headache, dry mouth, constipation.

If one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, you must consult a doctor.

Side effects and drug interactions in children:

Parents must inform the attending doctor about any side effects, as well as any additional medicine being given to the child!

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.
- Store in a cool and dark place below 25°C.
- Use the preparation within 6 months after first opening it.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
Purified water, sucrose, honey 375 mg, alcohol 96%, caramel, citric acid anhydrous, vanillin, orange flavor, cherry flavor, eucalyptus oil.
Each 5 ml of syrup contains 3 grams of sucrose and 3.2 mg sodium.
- **What does the medicine look like and what are the contents of the package?**
The package contains 115 ml of caramel-brown syrup.
- **Manufacturer and registration holder:** Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000 Israel.
- This leaflet was checked and approved by the Ministry of Health in July 2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 131.32.31021.00

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