

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription

Kufsyrup Syrup

Active ingredients

Each 1 ml contains:

ephedrine hydrochloride	1.2 mg
dextromethorphan hydrobromide	1 mg
potassium guaiacolsulphonate	24 mg
sodium benzoate	4 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within 7 days.

This medicine is not indicated for use in children under 12 years of age.

1. What is this medicine intended for?

This medicine is intended to relieve a cough in adults and adolescents from the age of 12 years and older.

Therapeutic group:

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

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this 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 an SSRI (selective serotonin reuptake inhibitor, such as fluoxetine).
- If you are suffering from problems with liver function.
- In children under 12 years of age.

Special warnings about using this medicine

- Do not use this medicine frequently or for a prolonged period without consulting a doctor.

Do not use this medicine without consulting your doctor before beginning treatment:

- if you are suffering or have previously suffered 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 gland.
- if you are suffering or have previously suffered from allergy (especially a medication allergy), from diabetes.
- in case of prolonged cough due to smoking or any problem involving the respiratory system, such as: asthma, emphysema, COPD (chronic obstructive pulmonary disease) or a cough accompanied by a lot of phlegm (see also section "Do not use this medicine").

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

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

Using this 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 using machines

Using the medicine may impair alertness and/or vision. Therefore, you must exercise caution when driving a car, operating dangerous machinery, and during any activity that requires alertness.

Smoking

If you smoke, inform your doctor before starting treatment with this medicine.

Important information about some of this medicine's ingredients

This medicine contains ethanol, sucrose and sodium.

Ethanol - the medicine contains 5.2% v/v ethanol (alcohol). Each 1 ml contains 44.4 mg ethanol. Total ethanol in the package: 5,106 mg.

Sucrose - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This syrup may also harm the teeth.

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

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually:

Adults and adolescents above 12 years of age: 10 ml three times a day and 10 ml at night before going to bed.

This medicine is not intended for children under the age of 12.

Attention: Be sure to measure the dose in the special measuring cup.

Do not exceed the recommended dose.

If your condition does not improve within 7 days, contact your doctor.

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

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

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Kufsyrup may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop use and contact your 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 your fingertips or toes, nausea, decrease/increase in heart rate.

Additional side effects

Common side effects:

Dizziness, upset stomach, drowsiness.

(Side effects of known significance (the frequency of these effects has not been established yet):

Headache, dry mouth, constipation.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

Side effects may also be reported to safety@trima.co.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/label. The expiry date refers to the last day of that month.
- Store in a dark and cool place, below 25°C.
- After first opening of the bottle, the medicine can be used within 6 months and no later than the expiry date.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Purified water, sucrose, honey 375mg, alcohol 96%, caramel, citric acid anhydrous, vanillin, orange flavor, cherry flavor, eucalyptus oil.

What the medicine looks like and contents of the pack?

The package contains a bottle with 115 ml of caramel-brown syrup. The bottle is child resistant.

Registration holder's, manufacturer's name and address: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

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Registration number of the medicine in the Ministry of Health's National Drug Registry:

176-34-37847-99

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.

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