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

This medicine is dispensed without a doctor's prescription

Tiptipot Mucolit 75 mg/ml



Oral drops

The active ingredient and its concentration: Carbocysteine 75 mg/ml Each drop contains 5 mg of carbocysteine.

refer to the doctor or the pharmacist

For inactive ingredients and allergens in the preparation, see the section "Important information about some ingredients of the medicine" and section 6. Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions.

The medicine is not intended for children under the age of 2. Below this age — contact the doctor. Use the preparation 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 after 7 days.

Tiptipot Mucolit is intended especially for children.

1. What is the medicine intended for?

The medicine is intended for relief in respiratory system disorders accompanied by excessive and/or viscous mucus

Therapeutic class: expectorants

2. Before using the medicine:

Do not use this medicine if

- The child is under 2 years of age.
 There is a known sensitivity (allergy) to carbocysteine or to any of the additional ingredients the medicine contains (see section 6). Signs of allergic reaction include: rash, breathing or swallowing problems, swelling of the lips, face, throat or tonque.
- In case of a gastric or intestinal ulcer.

■ Special warnings regarding the use of the medicine:

Before treatment with Tiptipot Mucolit, inform the doctor if:

The child has had a gastric or intestinal ulcer in the past

■ Drug-drug interactions:

If the child is taking or has recently taken other medicines, including non-prescription medicines and dietary supplements, tell the doctor or pharmacist. Especially if the child is taking:

• Other medicines that may cause gastric bleeding

Pregnancy, breastfeeding and fertility:

Tiptipot Mucolit is intended especially for children. If you are an adult using this medicine, do not use the medicine without consulting a doctor prior to starting the treatment if you are pregnant, might be pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

Use of Mucolit is not recommended during pregnancy and breastfeeding.

■ Important information about some ingredients of the medicine:

Each 1 ml of the medicine contains 280 mg of sorbitol, which is equivalent to 18.7 mg of sorbitol in each drop. Sorbitol is a source of fructose. If you have been told by the doctor that the child has intolerance to certain sugars or that he had been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which a person cannot metabolize fructose, consult the doctor before administering the medicine.

Sorbitol may cause digestive system discomfort and diarrhea.

Each 1 ml of the medicine contains about 15 mg of sodium, which is equivalent to 0.75% of the maximum daily intake recommended for adults.

The preparation contains parabens, which may cause an allergic reaction (even after some time).

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. The generally accepted dosage is:

Patient age	Dose in drops	Maximum number of doses
2-5 years	12-25 drops	4 times per day
6-12 years	50 drops	3 times per day

Accepted dosage for children based on weight: Children at the same age may have significantly

Children at the same age may have significantly different weights. That is why it is recommended to determine the dosage per weight according to the calculation below.

4-5 drops (20-25 mg) per kg body weight per day. The total dose should be divided into 3-4 doses during the day, according to age, as specified in the dosage table.

Do not exceed the recommended dose Duration of treatment:

If no improvement in the condition is felt within 7 days,

contact the doctor. However, if the condition is getting worse during treatment, contact the doctor before the 7 days of treatment are over.

<u>Attention:</u> be sure to measure the dose with the dropper.

Method of use:

- Do not shake the medicine before use shaking makes it difficult for the drops to leave the dropper.
- The original dropper is calibrated to release a measured and accurate amount with each use. Do not replace the original dropper with another.
- Open the cap 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 the bottom of the bottle lightly (see figure 3).
- Count the drops precisely.
- 7. Pour the measured content of the spoon into the patient's mouth.

Do not pour the medicine directly from the bottle into the mouth!

Wipe the bottle's top (the dropper). Be sure to put the cap on tightly immediately after you finish using the medicine in order to prevent the dropper from clogging.

If the child accidentally took a higher dosage, he may suffer from indigestion (digestive system disturbances).

if the child has taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to administer the medicine at the required time, do not administer a double dose. Administer the next dose at the regular time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> 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 Mucolit may cause side effects in some users. Do not be alarmed when reading the list of side effects. The child may not suffer from any of them.

Stop using the medicine and immediately refer to a doctor or to a hospital emergency room in the following cases:

- An allergic reaction. Signs include: rash, breathing or swallowing problems, swelling of the lips, face, throat or tongue.
- Appearance of blisters or bleeding on the skin,

including around the lips, eyes, mouth, nose and genitalia. These effects may be accompanied by flu-like symptoms and fever - these may indicate Stevens-Johnson syndrome.

Bloody vomit, tar-black stool.

Tell the doctor or pharmacist if any of the following side effects worsens or lasts longer than a few days:

- Nausea or vomiting
 Diarrhea
- Diaimea
- · Abdominal pain

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. Reporting side effects:

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. Once the bottle has been opened, Tiptipot Mucolit may be used for 2 months.

6. Additional information:

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

Sorbitol Solution 70%, Sodium Carbonate Decahydrate, Sodium Citrate, Citric Acid, Sodium Methyl Hydroxybenzoate, Cream Essence, Saccharin Sodium, Sodium Propyl Hydroxybenzoate, Disodium Edetate, Purified Water.

What does the medicine look like and what are the contents of the package:

A glass bottle containing 15 ml of yellow-brown solution with caramel flavor.

Manufacturer/license holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi. This leaflet was revised in 01/2021 in accordance with the Ministry of Health quidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1225430239







