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

This medicine is dispensed without a doctor's prescription

Mucolit Oral Solution 250 mg/5 ml

The active ingredient and its concentration:
Carbocysteine 250 mg/5 ml
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, refer to the doctor or the pharmacist.
The medicine is not intended for children under the age of 2. 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 after 7 days.

1. What is the medicine intended for?

The medicine reduces the viscosity of the mucus and acts as expectorant. 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:

- You are sensitive (allergic) 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 tongue.
- You have a gastric or intestinal ulcer.

Special warnings regarding the use of the medicine:
Before treatment with Mucolit 250 Oral Solution, inform the doctor if:

- You are elderly
- You have had a gastric or intestinal ulcer in the past

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

- Other medicines that may cause gastric bleeding

Pregnancy, breastfeeding and fertility:
Use of Mucolit is not recommended during pregnancy and breastfeeding.
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.
Important information about some ingredients of the medicine:
The solution contains maltitol. If you have been told by the doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.
Each 5 ml of the solution contains about 38 mg of sodium, which is equivalent to 1.9% of the maximum daily intake recommended for adults.
Each 5 ml of the solution contains 32.5 mg of propylene glycol.
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 milliliters	Maximum number of doses
2-5 years	1.25-2.5 ml	4 times per day
6-12 years	5 ml	3 times per day
Adults and children over the age of 12 years	15 ml and when there is an improvement the dosage may be reduced to 10 ml	3 times per day

Accepted dosage for children based on weight:
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.
0.4-0.5 ml (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 your condition is felt within 7 days, contact the doctor. However, if your condition is getting worse during treatment, you should contact the doctor before the 7 days of treatment are over.
Method of administration: Oral solution.
Wash the measuring cup before each use.
You should use a measuring spoon or a syringe that is designated for measuring the proper amount of medicine. If a spoon or any other measuring device was not provided with the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in their sizes and you may not receive the appropriate amount of medicine.
If a dosage lower than 2.5 ml is required, use a suitable device for measurement (e.g. a syringe), which can be purchased from a pharmacy, or use a Tiptipot Mucolit preparation.
Child-proof safety caps have significantly reduced the number of poisoning incidents caused by medicines each year. However, if you find it difficult to open the package, you can refer to a pharmacist to ask to have the safety mechanism removed and to turn the cap into a regular, easy-to-open cap.
If you accidentally took a higher dosage, you may suffer from indigestion (digestive system disorders).
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 forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a 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 Mucolit 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.
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
- 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, in the original package. Do not freeze.
Once the bottle has been opened, the solution may be used for 6 months.

6. Additional information:

In addition to the active ingredient, the medicine also contains:
Maltitol Solution, Sodium Hydroxide, Sodium Citrate Dihydrate, Propylene Glycol, Hydroxyethyl Cellulose, Sodium Methyl Hydroxybenzoate, Strawberry Flavor, Citric Acid, Saccharin Sodium, Sodium Propyl Hydroxybenzoate, Purified Water.
What does the medicine look like and what are the contents of the package:
A glass bottle containing 110 ml of a clear, slightly viscous, colorless to yellowish solution with strawberry odor.
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 guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health: 157-41-34597.

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