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

This medicine is dispensed without a doctor's prescription

Mucolit 375 mg Lozenges Honey-Lemon Flavour

The active ingredient and its quantity:

Each lozenge contains: carbocysteine 375 mg
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. 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, 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.

$\ensuremath{\boldsymbol{H}}$ Important information about some ingredients of the medicine

Each lozenge contains less than 23 mg of sodium, and is therefore considered sodium-free.

The lozenge contains Sunset Yellow, which may cause allergic reactions.

The lozenge contains 10.5 mg of aspartame. Aspartame is a source of phenylalanine. This may be dangerous for patients with phenylketonuria, a rare genetic disorder in which phenylalanine accumulates in the body.

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:

2 lozenges, 3 times a day. Once an improvement is felt, the dose may be reduced to one lozenge 4 times a day. The medicine is not intended for children. There are other forms of administration for children, e.g., Mucolit Oral Solution, Tiptipot Mucolit.

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: The lozenges should be sucked on or chewed.

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 <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 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, the 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 a syndrome called 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.

6. Additional information:

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

Xylitol, Sodium Starch Glycolate, Polyvinylpyrrolidone, Magnesium Stearate, Microcrystalline Cellulose, Aspartame, Lemon Flavour, Honey Flavour, Quinoline Yellow 70-E104. Sunset Yellow FCF E110.

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

The package contains blisters containing 12, 18, 24, 36 lozenges. Each lozenge is round, flat, orange coloured and honey-lemon flavored. Not all package sizes may be marketed

Manufacturer/license holder and address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi. This leaflet was reviewed and approved by the Ministry of Health in 06/2016 and has been updated in accordance with the Ministry of Health instructions in 01/2021.

Registration number of the medicine in the national drug registry of the Ministry of Health: 142022973601

