<u>Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)</u> - 1986

This medicine is dispensed without a doctor's prescription

Mical tablets

Active ingredient and quantity: Each tablet contains: carbocysteine 375 mg

Inactive ingredients and allergens in the preparation - see section 6.

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 a pharmacist if you need additional information. Consult your doctor if the symptoms of the disease worsen or do not improve after 7 days.

1. What is this medicine intended for?

The medicine reduces the viscosity of the mucus and acts as an expectorant. The medicine is intended to relieve respiratory system disorders accompanied by excessive and/or viscous mucus discharge.

Therapeutic group: expectorants

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to carbocysteine or to any of the other ingredients in this medicine (see section 6). Signs of an 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 about using this medicine Before treatment with Mical tablets, tell your doctor if:

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

Drug interactions

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

Other medicines that may cause gastric bleeding

Pregnancy and breastfeeding

Use of Mical tablets is not recommended during pregnancy and breastfeeding. If you are pregnant, might be pregnant, planning to become pregnant, breastfeeding or planning to breastfeed, do not use this medicine before you consult your doctor.

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:

2 tablets, 3 times a day. Once there is improvement, the dose may be reduced to one tablet 4 times a day.

Do not exceed the recommended dose.

Duration of treatment:

If your condition does not improve within 7 days, contact your doctor. However, if your condition worsens during treatment, you should contact your doctor before the 7 days of treatment are over.

Method of administration: Swallow the medicine with a small amount of water. You may split or crush the tablets immediately before taking them. Do not store split or crushed tablets.

If you have accidentally taken a higher dose, you may suffer from indigestion (digestive system disorders).

If you have taken an overdose 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 regular time and consult your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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:

Like with all medicines, using Mical tablets 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 using this 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.
- 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.

Inform 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 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.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.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 a doctor.
- Do not use the medicine after the expiry date (exp.) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C.

6. Additional information:

In addition to the active ingredient, this medicine also contains: microcrystalline cellulose, starch pregelatinised, povidone, sodium starch glycolate, colloidal silicone dioxide, magnesium stearate.

What the medicine looks like and contents of the pack:

A package containing 20 white tablets packaged in 2 trays.

Manufacturer and registration holder's name and address:

Sam-On Ltd., 25 Ehud Kinamon (Haavoda) Street, Bat Yam.

This leaflet was revised in 07/2021 according to MOH guidelines.

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

121-18-30069-00