PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [S1]

MUCO-ACYST 200 (effervescent tablets)

200 mg of acetylcysteine /effervescent tablet

MUCO-ACYST 200 is sugar free.

MUCO-ACYST 200 contains sweetener (saccharin sodium 20.0 mg /effervescent tablet)

Read all of this leaflet carefully before you start taking MUCO-ACYST 200

- MUCO-ACYST 200 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MUCO-ACYST 200 carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share MUCO-ACYST 200 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What MUCO-ACYST 200 is and what it is used for
2. What you need to know before you take MUCO-ACYST 200
3. How to take MUCO-ACYST 200
4. Possible side effects
5. How to store MUCO-ACYST 200
6. Contents of the pack and other information

1. What MUCO-ACYST 200 is and what it is used for

MUCO-ACYST 200 is used to dissolve thick mucous (phlegm) in respiratory conditions.

2. What you need to know before you take MUCO-ACYST 200

Do not take MUCO-ACYST 200:

- if you are allergic to acetylcysteine or any of the other ingredients of this medicine listed in section 6.
- If you are pregnant or plan to become pregnant, or if you are breastfeeding your baby.
- Do not give MUCO-ACYST 200 effervescent tablets to children under 2 years of age.

Take special care with MUCO-ACYST 200

- If you have asthma.
- If you are elderly with lung problems such as respiratory insufficiency (a condition in which the lungs cannot take in sufficient oxygen or expel sufficient carbon dioxide to meet the needs of the cells of the body).
- If you have a history of stomach ulcers.

Do not take MUCO-ACYST 200 effervescent tablets continuously for more than 14 days without consulting a doctor.

Other medicines and MUCO-ACYST 200

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Antibiotics, as these must be taken at least two hours before or after MUCO-ACYST 200
- Cough medicines
- Activated charcoal

- Nitroglycerin which is used to stop or prevent angina (chest pain)

MUCO-ACYST 200 with food and drink

MUCO-ACYST 200 should be dissolved in a glass of water before use.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety and/or efficacy has not been established, therefore you should not use MUCO-ACYST 200 during pregnancy and breastfeeding (see “Do not take MUCO-ACYST 200” above).

Driving and using machinery

MUCO-ACYST 200 has no known effect on the ability to drive and use machines. However, it is not always possible to predict to what extent any medicine may interfere with the daily activities of a patient. Patients should therefore ensure that they do not engage in the above activities until they are aware of the measure to which MUCO-ACYST 200 affects them.

3. How to take MUCO-ACYST 200

Do not share medicines prescribed for you with any other person.
Always take MUCO-ACYST 200 exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Do not to swallow the tablet whole.
- Do not chew the tablet.
- Dissolve the effervescent tablet in one glass of water, then drink the contents of the whole glass.

The usual dose for:

- Children 2 to 5 years:

  Give ½ (half) MUCO-ACYST 200 effervescent tablet 2 to 3 times a day.

- Children 6 to 14 years:

  Give one MUCO-ACYST 200 effervescent tablet twice daily.

- Adults and children from 14 years of age:

  Take one MUCO-ACYST 200 effervescent tablet 2 to 3 times a day.

Do not take MUCO-ACYST 200 continuously for more than 14 days without consulting a doctor.
If you have the impression that the effect of MUCO-ACYST 200 effervescent tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more MUCO-ACYST 200 than you should

If you take too many tablets you may feel nauseous, vomit and/or have diarrhoea.
If you take too much **MUCO-ACYST 200**, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MUCO-ACYST 200

If you have missed a dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take

MUCO-ACYST 200 at the next scheduled time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

MUCO-ACYST 200 can have side effects.

Not all side effects reported for **MUCO-ACYST 200** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MUCO-ACYST 200**, please consult your health care provider for advice.

If any of the following happens, stop taking MUCO-ACYST 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Severe allergic reactions (anaphylaxis).

Allergic reaction causing swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to MUCO-ACYST 200. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice/experience any of the following:

- Changes in the way your heart beats, for example, if you notice it beating faster.
- Fits (convulsion)
- Low blood pressure/fainting
- Difficulty breathing or fast breathing.

These are all serious side effects. You may need urgent medical attention.

Less frequent side effects

- Bleeding from vessels
- Headache.
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Runny nose
- Sores inside your mouth stomach pain, diarrhoea, vomiting, heartburn, nausea and indigestion.
- Rash, itching or hives.
- Fever or chills.

Other side effects for which the frequency is unknown

- a sudden, sometimes temporary, stop of the heart's functioning (cardiac arrest)
- stop of breathing and coughing up of blood or blood-stained mucus
- blurred vision
- flushing and sweating
- Joint pain

Other side effects for which the frequency is unknown that may show up in blood tests:

- disturbances of liver function
- an excessively acid condition of the body fluids or tissues (acidosis)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible

side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found on-line under SAHPRAs publications: https://www.sahpra.org.za/Publications/Index/8.Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of MUCO-ACYST 200.

5. How to store MUCO-ACYST 200

- Store at or below 25 °C in a cool dry place.
- Protect from light.
- Keep tablets in the tube until required for use.
- KEEP THE TUBE TIGHTLY CLOSED.
- KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MUCO-ACYST 200 contains

- The active substance is:

  acetylcysteine
- The other ingredients are:

  maltodextrin, citric acid anhydrous, sodium hydrogen carbonate, leucine and orange flavour.

  MUCO-ACYST 200 contains sweetener (saccharin sodium).

What MUCO-ACYST 200 looks like and contents of the pack

MUCO-ACYST 200: White to off white round, flat tablets.

Upon dissolving in water: Slightly opalescent, colourless solution.

MUCO-ACYST 200 are packed in plastic tubes closed with stoppers equipped with silica gel as a drying agent. The tube is inserted into cardboard boxes with the leaflet.

MUCO-ACYST 200:

Pack size:

- Cardboard box containing a tube of 10 tablets.
- Cardboard box containing one or two tubes of 20 tablets each.

Holder of Certificate of Registration

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