PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

MUCOTRIN 200 mg effervescent tablet

Acetylcysteine

Sugar: saccharin

Read all of this leaflet carefully because it contains important information for you

MUCOTRIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **MUCOTRIN** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

- Do not share **MUCOTRIN** 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 **MUCOTRIN** is and what it is used for
2. What you need to know before you take **MUCOTRIN**
3. How to take **MUCOTRIN**
4. Possible side effects
5. How to store **MUCOTRIN**
6. Contents of the pack and other information

1. What MUCOTRIN is and what it is used for

MUCOTRIN thins mucous and makes it easier to cough up.

2. What you need to know before you take MUCOTRIN

Do not take MUCOTRIN

- If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of **MUCOTRIN** (listed in section 6).
- If you are pregnant or breastfeeding

Do not give **MUCOTRIN** to children under 2 years of age.

Warnings and precautions

Take special care with **MUCOTRIN**:

- If you have asthma as **MUCOTRIN** may cause bronchospasm
- If you are an elderly person with lung problems
- If you have a history of ulcers as **MUCOTRIN** may affect mucous membranes.
- If you have a histamine intolerance
- If you are unable to cough up your secretions as the mucous is too much and too fluid you will need to see you doctor.
- If you smell a mild sulphurous smell, there is nothing wrong with the product it is a characteristic of the active ingredient.

Stevens-Johnson syndrome and toxic epidermal necrolysis are serious disorders of the skin which have been reported. Tell your doctor if you develop:

High fever and flu-like symptoms followed by flat red spots on your skin, blisters then form.

Painful blistering of the mucous membranes, like mouth and eyes.

Other medicines and MUCOTRIN

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

These could include: nitroglycerins (medicine used for heart conditions), medicines that stop you from coughing called antitussives, activated charcoal and antibiotics.

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. You should not take **MUCOTRIN** if you are pregnant or breastfeeding.

Driving and using machines

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **MUCOTRIN** affects them. **MUCOTRIN** should have no effect on the ability to drive.

3. How to take MUCOTRIN

Do not share medicines prescribed for you with any other person.

Always take **MUCOTRIN** exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose for adults is one tablet 2-3 times a day.

Children from 2 to 5 years of age: Half a tablet 2-3 times daily

Children from 6 to 14 years of age: One tablet twice daily

Dissolve the effervescent tablet in one glass of water. Then drink the contents of the whole glass.

If you take more MUCOTRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MUCOTRIN

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MUCOTRIN can have side effects.

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

If any of the following happens, stop taking / using **MUCOTRIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your face, lips or throat, difficulty breathing.
- Flat red rash all over your body
- Painful mouth or eyes

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Ringing in your ears
- Headache
- Runny nose
- Vomiting

- Nausea
- Diarrhoea
- Indigestion, stomach pain, heartburn
- Fever
- Rash
- Difficulty breathing
- Fast heart beat
- Blurred vision
- Heart pain
- Chills
- Low blood pressure
- Haemorrhages (bleeding)

Side effects which may occur with unknown frequency:

- Fainting
- Seizures (fits)
- Cardiac arrest
- Flushing, sweating
- Coughing up blood
- Respiratory arrest
- Liver function problems
- Swelling of the face
- Joint pain

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

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **MUCOTRIN**.

5. How to store MUCOTRIN

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in the original package/ container
- Keep the container tightly closed
- Protect from moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label

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 MUCOTRIN contains

- The active substance is acetylcysteine
- The other ingredients are maltodextrin, citric acid anhydrous, sodium hydrogen carbonate, saccharin sodium dihydrate, orange flavour, leucine.

What MUCOTRIN looks like and contents of the pack

White to off white round, flat effervescent tablets are provided in a tube of 20.

Tablets are kept in a polypropylene tube closed with a polyethylene stoppers

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equipped with silica gel as drying agent.

Holder of Certificate of Registration

Trinity Pharma

106 16th Road

Midrand

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This leaflet was last revised in

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Registration number

Access to the corresponding Professional Information

The PI is contained in the packaging of a medicine.

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