APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

MUCOFIZZ 200 effervescent tablets

Acetylcysteine

Sugar free

Contains sweetener (saccharin sodium 20 mg)

Read all of this leaflet carefully before you start taking MUCOFIZZ 200

MUCOFIZZ 200 is available without a doctor's prescription,

for you to treat a mild illness. Nevertheless, you still need to use

MUCOFIZZ 200 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MUCOFIZZ 200 with any other person.
- Ask your healthcare 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 MUCOFIZZ 200 is and what it is used for

MUCOFIZZ 200 contains the active substance acetylcysteine, which is made from a natural amino acid. Acetylcysteine belongs to a group of medicines called mucolytics which work by thinning the mucus (phlegm) so that it can be coughed up easily. MUCOFIZZ 200 is used to dissolve thick mucus (phlegm) in the lungs and airways that can clog the lungs and affect breathing. MUCOFIZZ 200 should not be used for more than 14 days.

2. What you need to know before you take MUCOFIZZ 200

Do not take MUCOFIZZ 200:

- if you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of MUCOFIZZ 200 (see section 6)
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you have active peptic ulceration
- do not use MUCOFIZZ 200 in children under the age of 2 years.

Warnings and precautions

Take special care with MUCOFIZZ 200:

- if you notice any changes to your skin such as those seen in Stevens-Johnson syndrome and Lyell's syndrome, which is characterised by severe skin reactions, stop treatment and seek medical advice immediately

- if you suffer from asthma, as you may need to be closely monitored whilst taking MUCOFIZZ 200
- if you are elderly and have trouble breathing
- if, before you begin taking MUCOFIZZ 200, you are unable to cough then you may need to have the mucus removed by suction after MUCOFIZZ 200 has loosened it
- if you have a history of stomach ulcers or have a stomach ulcer (symptoms include nausea, vomiting, heartburn, bloating, burning pain in your stomach between meals or at night) as MUCOFIZZ 200 may affect your stomach lining
- if you have a condition in which the liver does not function properly (cirrhosis) you may need to be monitored closely, as you are more likely to experience allergic reactions and other side effects (see section 4). Symptoms of cirrhosis may include fatigue, bleeding easily, bruising easily, itchy skin, yellow discolouration in the skin and eyes, loss of appetite and nausea
- if you have histamine intolerance. If you are not able to tolerate food and drinks that contain large amounts of histamines, MUCOFIZZ 200 may not be suitable for you, because it affects how histamines are broken down in the body. The most common symptoms of histamine intolerance are headaches, runny nose and itching
- if you are due to have any blood or urine tests, as MUCOFIZZ 200 can interfere with some laboratory tests.

Children

Do not give MUCOFIZZ 200 to children under the age of 2 years (see Do not take MUCOFIZZ 200).

Other medicines and MUCOFIZZ 200

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

Tell your doctor, pharmacist or healthcare provider if you are taking the following:

- antitussive medicines used to stop coughs as the combined use with MUCOFIZZ 200 may decrease your cough reflex and cause a build-up of mucus (phlegm)
- antibiotics (used to treat bacterial infections) must not be taken at the same time as, MUCOFIZZ 200 can prevent some antibiotics from working properly. If you are taking antibiotics, you should take MUCOFIZZ 200 either two hours before or two hours after your antibiotic
- activated charcoal, used to treat poisoning, may reduce the effects of MUCOFIZZ 200
- medicines such as nitro-glycerine/glyceryl trinitrate to treat angina attacks, (tightness in your chest, neck and arm) as this combination may cause a severe decrease in blood pressure together with a headache. Your doctor may need to monitor you
- if you are taking carbamazepine (for epilepsy), inform your doctor or pharmacist as MUCOFIZZ 200 may alter the effects of carbamazepine.

MUCOFIZZ 200 with food and drink

MUCOFIZZ 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 healthcare provider for advice before taking MUCOFIZZ 200.

You should not take MUCOFIZZ 200 if you are pregnant or breastfeeding your baby (see Do not take MUCOFIZZ 200). The safe and effective use in pregnancy and during breastfeeding has not been confirmed.

Driving and using machines

MUCOFIZZ 200 should not affect your ability to drive or operate machinery. However, it is not always possible to predict to what extent MUCOFIZZ 200 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MUCOFIZZ 200 affects them.

3. How to take MUCOFIZZ 200

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

Always take MUCOFIZZ 200 exactly as described in this leaflet or as your doctor has told you.

Check with your doctor or pharmacist if you are unsure.

Adults and adolescents from 14 years of age

The usual dose is one (1) effervescent tablet two to three times daily.

Children from 6 to 14 years of age

The usual dose is one (1) effervescent tablet twice daily for a maximum of 14 days.

Children from 2 to 5 years of age

The usual dose is half (½) an effervescent tablet two to three times daily for a maximum of 14 days.

Do not use MUCOFIZZ 200 continuously for more than 14 days without consulting a doctor.

Dissolve the MUCOFIZZ 200 effervescent tablet in a glass of water. Then drink the contents of the whole glass.

If you have the impression that the effect of MUCOFIZZ 200 is too strong or too weak, tell your doctor or pharmacist.

If you take more MUCOFIZZ 200 than you should

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

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

Symptoms of overdose may include nausea, vomiting and diarrhoea.

Infants are at risk of hypersecretion.

If you forget to take MUCOFIZZ 200

If you forget to take MUCOFIZZ 200, take a dose as soon as you remember. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MUCOFIZZ 200 can have side effects.

Not all side effects reported for MUCOFIZZ 200 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using MUCOFIZZ 200, please consult your healthcare provider for advice.

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If any of the following happens, stop using MUCOFIZZ 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching, hives
- rapid, weak pulse; skin rash; nausea, vomiting, difficulty breathing and shock (anaphylactic reactions).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MUCOFIZZ 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 any of the following:

- flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters (Stevens-Johnson syndrome)
- fever and flu-like symptoms with severe skin peeling and blistering resulting in painful raw areas (toxic epidermal necrolysis)
- fainting, blackouts, dizziness, chest pain, shortness of breath or vomiting which may be signs of heart failure
- inability to breathe, bluish colouration in skin; fingertip; or lips, restlessness, rapid; shallow breathing or racing heart which may be signs of lung failure
- seizure (fits)
- coughing up blood

- trouble breathing, coughing, shortness of breath, chest tightness or pressure which may be signs of narrowing airways
- severe bleeding, abdominal pain, blood in the stool, blood in the urine, vomiting blood, chest pain and abdominal swelling which may be signs of a haemorrhage
- irregular heartbeat, fast heart rate, fatigue, increased rate and depth of breathing, confusion, and headaches, which may lead to seizures (acidosis).

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- headache
- ringing or buzzing sound in the ears (tinnitus)
- faster than normal heart rate
- low blood pressure (characterised by dizziness or light-headedness, fainting, weakness, fatigue, pale skin)
- runny nose
- abdominal pain, diarrhoea, nausea, vomiting, inflammation inside the mouth, heartburn
- chills, fever.

Side effects with unknown frequency:

- fainting
- blurred vision
- high blood pressure (characterised by severe headache, fatigue or confusion, vision problems, irregular heartbeat)

- flushing (feelings of warmth and rapid reddening of your neck, upper chest or facial region), sweating
- pain in the upper right part of your abdomen, yellow discolouration of the skin (jaundice), which are indications of disturbances in liver function
- swelling of the face
- joint pain.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of MUCOFIZZ 200.
You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store MUCOFIZZ 200

Store all medicines out of reach of children.

Store at or below 25 °C

Protect from light and moisture. Store in the original tube and keep the tube tightly closed when not in use.

Do not use after the expiry date stated on the carton.

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 MUCOFIZZ 200 contains

The active substance is acetylcysteine.

Each effervescent tablet contains 200 mg acetylcysteine.

Sugar free.

Contains sweetener (saccharin sodium 20 mg).

The other ingredients are:

Citric acid, leucine, maltodextrin, orange flavour, saccharin sodium and sodium hydrogen carbonate.

What MUCOFIZZ 200 looks like and contents of the pack

Before reconstitution:

White to off white round, flat tablets.

After reconstitution:

Slightly opalescent, colourless solution.

MUCOFIZZ 200 tablets are packed in a polypropylene tube closed with a polyethylene stopper equipped with silica gel. Each tube contains 10 or 20 effervescent tablets and 1 or 2 tubes are packed in an outer carton.

Not all pack sizes are marketed in South Africa.

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Holder of Certificate of Registration

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