

**SCHEDULING STATUS:** **S1**

**ACC 200 (effervescent tablets)**

Acetylcysteine

Contains sugar (lactose anhydrous 70 mg) and mannitol 60 mg

Contains sweetener (saccharin sodium 6 mg)

**Read all of this leaflet carefully before you start taking ACC 200**

ACC 200 effervescent tablets are available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use ACC 200 effervescent tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACC 200 effervescent tablets 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 ACC 200 is and what it is used for
2. What you need to know before you take ACC 200
3. How to take ACC 200
4. Possible side effects
5. How to store ACC 200
6. Contents of the pack and other information

**1. What ACC 200 is and what it is used for**

ACC 200 belongs to a group of medicines called mucolytics, which work by thinning the mucous (phlegm) so that it can be coughed up more easily.

**2. What you need to know before you take ACC 200**

**Do not take ACC 200 effervescent tablets:**

- If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of ACC 200 effervescent tablets (listed in section 6).
- If you have a history of stomach ulcers.
- If you are pregnant or plan to become pregnant. Please consult with your doctor.
- Do not give ACC 200 effervescent tablets to children under 2 years of age.
- Do not use ACC 200 effervescent tablets continuously for more than 14 days without consulting a doctor.

### **Warnings and precautions**

#### ***Take special care with ACC 200 effervescent tablets:***

- If you have asthma.
- If you have a history of ulcers, especially if you are taking other medicines known to irritate the lining of the digestive tract.
- If you are intolerant to histamine. If you are not able to tolerate food and drinks that contain large amounts of histamine, ACC 200 may not be suitable for you, because it affects how histamine is broken down in the body. The most common symptoms of histamine intolerance are headaches, runny nose and itching.
- As the thick phlegm becomes more fluid, its volume will increase, especially at the beginning of the treatment. If you are unable to efficiently cough up this fluid phlegm, you must consult a doctor so that adequate measures can be taken to remove the phlegm.
- There have been very rare reports of serious hypersensitivity reactions with (high) fever, skin redness, joint pains and/or eye infection (Stevens-Johnson syndrome), and acute hypersensitivity reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell syndrome). If you develop a rash or these symptoms, you must immediately consult a doctor and stop using ACC 200.

### **Children and adolescents**

Do not use in children under the age of 2 years.

### **Other medicines and ACC 200**

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

Cough suppressants should not be used at the same time as ACC 200 effervescent tablets, as you must be able to cough up the loosened phlegm.

Do not take ACC 200 effervescent tablets at the same time as any antibiotics. Allow an interval of at least two hours between the antibiotics and ACC 200 effervescent tablets. This does not apply to the antibiotics, cefixime and loracarbef.

ACC 200 effervescent tablets may increase the blood pressure-lowering effect of nitroglycerine (a medicine used against tight painful feeling in the chest (angina pectoris)). Caution is advised.

If you use activated charcoal (a medicine against diarrhoea), it may decrease the effect of ACC 200 effervescent tablets.

ACC 200 effervescent tablets may affect a test for salicylate (such as aspirin) in the blood. It may also affect the results when testing for ketones in urine.

If you are using other medicines, do not dissolve them together with ACC 200 effervescent tablets.

#### **ACC 200 with food, drink and alcohol**

ACC 200 effervescent tablets should be dissolved in a glass of water before use.

#### **Pregnancy, breastfeeding and fertility**

- Safety of ACC 200 effervescent tablets during pregnancy and breastfeeding has not been established.
- 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 ACC 200 effervescent tablets.

#### **Driving and using machines**

None known.

### **ACC 200 contains lactose**

ACC 200 effervescent tablets contains lactose anhydrous. Patients with the rare hereditary conditions of lactose intolerance should not take ACC 200.

ACC 200 effervescent tablets contains lactose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

### **3. How to take ACC 200**

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

Always take ACC 200 effervescent tablets 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.

Before taking ACC 200 effervescent tablets dissolve the effervescent tablet in one glass of water and drink the whole contents of the glass.

If you have the impression that the effect of ACC 200 effervescent tablets is too strong or too weak, talk to your doctor or pharmacist.

Do not use ACC 200 effervescent tablets continuously for more than 14 days without consulting a doctor.

#### **The usual dose is:**

**Children 2 to 5 years:** Take ½ (half) ACC 200 effervescent tablet 2 to 3 times daily.

**Children 6 to 14 years:** Take one ACC 200 effervescent tablet twice daily.

**Adults and children older than 14 years:** Take one ACC 200 effervescent tablet 2 to 3 times daily.

#### **If you take more ACC 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.

The following are all symptoms of an overdose:

- Feeling or being sick and diarrhoea.

- Hypersecretion (excessive production of bodily secretions, like stomach acid, mucus, or certain hormones) in children.

#### **If you forget to take ACC 200**

If you forget to take a dose, take it as soon as you remember.

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

Continue to take the next dose at the usual time.

#### **4. Possible side effects**

ACC 200 effervescent tablets can have side effects.

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

**If any of the following happens, stop taking ACC 200 effervescent tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Allergic reaction causing swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing, rash or itching.
- There have been very rare reports of serious hypersensitivity reactions with (high) fever, skin redness, joint pains and/or eye infection (Stevens-Johnson syndrome), and acute hypersensitivity reactions accompanied by fever and blisters on the skin or peeling of the skin (Lyell syndrome).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ACC 200 effervescent tablets. 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:**

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

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
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Bleeding
- Stomach pain
- Sores inside your mouth
- Diarrhoea
- Vomiting
- Heartburn
- Indigestion
- Nausea
- Rash, itching or hives
- Fever

***The frequency of the following side effects are unknown:***

- Swelling of the face

Different studies have found that the active component in ACC 200, acetylcysteine, may decrease the ability of your blood to clot.

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, 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 ACC 200.

Suspected side effects can also be reported directly to the HCR via [Patientsafety.sacg@novartis.com](mailto:Patientsafety.sacg@novartis.com).

**5. How to store ACC 200**

- Store at or below 25 °C in a cool dry place.
- **STORE ALL MEDICINES OUT OF REACH 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 and sewerage systems (e.g. toilets).

## **6. Contents of the pack and other information**

### **What ACC 200 effervescent tablets contain**

#### ***Active ingredient:***

Each ACC 200 effervescent tablet contains 200 mg acetylcysteine.

#### ***Inactive ingredients:***

Ascorbic acid, blackberry flavour "B", citric acid anhydrous, lactose anhydrous, mannitol, sodium hydrogen carbonate, sodium carbonate anhydrous, sodium citrate and saccharin sodium.

### **What ACC 200 looks like and contents of the pack**

ACC 200 are white round tablets, faultless, scored on one side (200 mg), smell of blackberries.

ACC 200 is packed in:

- Plastic tubes with a cap in an outer cardboard carton.
- Individually sealed laminated aluminium paper foil in an outer cardboard carton.

Note: pack sizes of either 20, 25 or 40 effervescent tablets.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Sandoz SA (Pty) Ltd<sup>1</sup>

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Magwa Crescent West

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Jukskei View

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**Access to the corresponding Professional Information**

Not applicable.

<sup>1</sup>Company Reg. No.: 1990/001979/07