

Applicant : Sandoz SA (Pty) Ltd
Proprietary name : ACC 200 POWDER FOR ORAL SOLUTION
Dosage form and strength : Powder for oral solution. Each sachet contains 200 mg acetylcysteine.
Date of submission : 13 February 2023

CLEAN PROPOSED PATIENT INFORMATION LEAFLET FOR ACC 200 POWDER FOR ORAL SOLUTION

SCHEDULING STATUS: S1

ACC 200 Powder for Oral Solution

Acetylcysteine

Contains sugar: sucrose (2717,00 mg) and saccharin (8,00 mg Saccharin).

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

ACC 200 powder for oral solution is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ACC 200 powder for oral solution carefully to get the best results from it.

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

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1. What ACC 200 powder for oral solution is and what it is used for

Each sachet of ACC 200 powder for oral solution contains the active substance acetylcysteine.

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

Acetylcysteine 200 powder for oral solution is used to treat breathing difficulties caused by too much mucus in the lungs and airways or the mucus being too thick and sticky to cough up easily.

2. What you need to know before you take ACC 200 powder for oral solution

Do not take ACC 200 powder for oral solution

- if you are hypersensitive, (allergic) to acetylcysteine or to any of the other ingredients of ACC 200 powder for oral solution (listed in section 6).
- if you are pregnant.

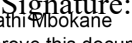
Warnings and precautions

Take special care with ACC 200 powder for oral solution:

- If you are an elderly patient with difficulty in breathing,
- If you are asthmatic,
- If you have or have a history of stomach ulcers,
- If you are due to have any blood or urine tests, as ACC 200 POWDER FOR ORAL SOLUTION can interfere with some laboratory tests.

On opening the sachet, ACC 200 powder for oral solution may smell of sulphur (rotten eggs). This is a normal characteristic of ACC 200 POWDER FOR ORAL SOLUTION and does not mean that it is not safe to use. Upon addition of water the solution will have citrus smell.

Other medicines and ACC 200 powder for oral solution

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

Tell your doctor or health care provider if you are taking any of the following medicines:

- Nitroglycerine or glyceryl trinitrate used for heart failure, high blood pressure and to treat and prevent chest pain from not enough blood flow to the heart (angina).
- Carbamazepine used in the treatment of epilepsy and mood disorders.
- Cough suppressants
- Activated charcoal.
- Antibiotics used to treat bacterial infections. Take ACC 200 POWDER FOR ORAL SOLUTION either two hours before or two hours after taking your antibiotics.

ACC 200 powder for oral solution with food, drink and alcohol

There are no special requirements to consider when taking ACC 200 powder for oral solution with food, drink or alcohol.

Pregnancy and breastfeeding

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-ACC 200 POWDER FOR ORAL SOLUTION.

Do not take ACC 200 POWDER FOR ORAL SOLUTION if you are pregnant.

Driving and using machines

It is not always possible to predict to what extent ACC 200 powder for oral solution 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 ACC 200 powder for oral solution affects them.

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ACC 200 powder for oral solution should be used with caution whilst driving and using machines as ACC 200 powder for oral solution may cause headaches.

Important information about some of the ingredients of ACC 200 powder for oral solution:

ACC 200 POWDER FOR ORAL SOLUTION contains sucrose and saccharin.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ACC 200 powder for oral solution.

ACC 200 powder for oral solution contains saccharin which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take ACC 200 powder for oral solution

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

Always take ACC 200 powder for oral solution 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 of ACC 200 powder for oral solution for the treatment of respiratory disorders:

Children up to 2 years: one sachet once daily

Children 2 to 6 years: one sachet twice daily

Adults: one sachet three times daily

Dissolve the powder in a glass of water. Then drink the contents of the whole glass.

If you take more ACC 200 powder for oral solution than you should

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

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The following are all symptoms of an overdose:

- Gastrointestinal symptoms such as nausea, vomiting and diarrhoea.

If you forget to take ACC 200 powder for oral solution

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

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

Continue to take the next dose at the usual time.

4. Possible side effects

ACC 200 powder for oral solution can have side effects.

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

If any of the following happens, stop taking ACC 200 powder for oral solution and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- severe bleeding, blistering, peeling, scaling or fluid filled patches on any part of your skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to ACC 200 powder for oral solution. 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:

- chest pain,

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- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty 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:

- Nausea, vomiting and diarrhoea,
- headache,
- buzzing, hissing, whistling, ringing or other persistent noise in the ears,
- an uncomfortable feeling in the stomach or belching after eating.
- fever,
- hives (urticaria),
- low blood pressure.

Frequency unknown side effects:

- runny nose,
- chills,
- spitting or coughing up of blood,
- swelling of the face

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

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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 powder for oral solution.

Suspected adverse reactions can also be reported directly to the HCR via patientsafety.sacg@novartis.com.

5. How to store ACC 200 powder for oral solution

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30 °C in a cool dry place.
- Once the contents of the sachet have been dissolved in water use this medicinal product immediately.
- Do not store the solution.
- Do not use after the expiry date stated on the sachet and 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 ACC 200 powder for oral solution contains

The active substance is acetylcysteine. Each sachet contains 200 mg acetylcysteine.

Inactive ingredients:

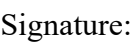
Sucrose

Ascorbic acid

Saccharin

Orange Flavour Dry 1:1000 Sotteri 289

What ACC 200 powder for oral solution looks like and contents of the pack

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ACC 200 powder for oral solution:

Homogeneous, white powder, free from agglomerations of particles, smell of orange.

When an ACC 200 powder for oral solution is dissolved in a glass of water, the appearance is clear to slightly opalescent, colourless solution in water.

Pack sizes:

The sachets are available in pack sizes of 10, 20, 25 or 40.

Not all pack sizes are marketed

The sachets are packed together with the leaflet into an outer cardboard carton

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd¹
Magwa Crescent West
Waterfall City
Jukskei View
Midrand
2090

This leaflet was last revised in

TBA

Registration numbers

ACC 200 POWDER FOR ORAL SOLUTION: To be allocated by SAHPRA upon registration

Access to the corresponding Professional Information

TBA

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