PROFESSIONAL INFORMATION

Scheduling status: S1

1 NAME OF THE MEDICINE

ACC® 20 mg/ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of ACC 20 mg/ml ORAL SOLUTION contains 20 mg acetylcysteine

Excipients with known effects:

Contains sweetener (saccharin sodium 1 mg per ml)

Contains preservatives (methyl parahydroxybenzoate 1,30 mg and sodium benzoate 1,95 mg per ml)

Contains benzyl alcohol, an ingredient of cherry flavour (0,1 mg per ml)

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution

Clear, slightly viscous, colourless solution with a cherry flavour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ACC 20 mg/ml Oral Solution is used as a mucolytic in acute respiratory conditions.

4.2 Posology and method of administration

Posology

The following dosage is recommended for ACC 20 mg/ml ORAL SOLUTION (if not otherwise prescribed):

Adults and adolescents over 14 years of age:

Take 10 ml oral solution 2 - 3 times daily (equivalent to 400 - 600 mg acetylcysteine per day).

Children and adolescents from 6 - 14 years of age:

Take 10 ml oral solution twice daily (equivalent to 400 mg acetylcysteine per day).

Children from 2 - 5 years of age:

Give 5 ml oral solution 2 - 3 times daily (equivalent to 200 - 300 mg acetylcysteine per day).

10 ml of oral solution is equivalent to half a measuring cup or the content of 2 filled syringes.

Method of administration

ACC 20 mg/ml ORAL SOLUTION is taken after meals.

It is taken by means of a syringe for oral preparation or measuring cup, included in the pack.

Duration of use:

ACC 20 mg/ml ORAL SOLUTION should not be taken for more than 14 days without consulting a doctor.

4.3 Contraindications

- Hypersensitivity to the active substance acetylcysteine, methyl-parahydroxybenzoate, sodium benzoate or to any of the inactive ingredients, see section 6.1
- Contraindicated in children below 2 years of age.
- Safety in pregnancy has not been established. ACC 20 mg/ml ORAL SOLUTION should not be used during pregnancy, see section 4.6.

4.4 Special warnings and precautions for use

- The occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell’s

syndrome has very rarely been reported in temporal connection with the use of ACC 20 mg/ml ORAL SOLUTION. If cutaneous and mucosal changes newly occur, medical advice should be sought without delay and the use of ACC 20 mg/ml ORAL SOLUTION be terminated, see section 4.8.

- Care should be exercised during use in patients with bronchial asthma and in patients with a history of ulcers.
- Caution is advised in patients with histamine intolerance. Longer-term therapy should be avoided in these patients as ACC 20 mg/ml ORAL SOLUTION affects the histamine metabolism and may lead to symptoms of intolerance (e.g. headache, vasomotor rhinitis, itching).
- The use of acetylcysteine, especially in early treatment can lead to liquefaction and thus to an increase in volume of bronchial secretions. If the patient is unable to cough up enough of this, appropriate measures (such as postural drainage and aspiration) should be performed.
- ACC 20 mg/ml ORAL SOLUTION contains methyl parahydroxybenzoate, sodium benzoate and benzyl alcohol.
- ACC 20 mg/ml ORAL SOLUTION contains 1,3 mg methyl parahydroxybenzoate in each ml. It may cause allergic reactions (possibly delayed).
- ACC 20 mg/ml ORAL SOLUTION contains up to 4,8 mg sodium in each ml, equivalent to 0,24 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- This medicinal product contains up to 0,1 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).
- Do not use continuously for more than 14 days without consulting a doctor.

- The safety and efficacy of ACC 20 mg/ml ORAL SOLUTION in children below 2 years has not been established. The use of ACC 20 mg/ml in children aged under 2 years is not recommended.
- Mucolytics can result in blockage of the respiratory tract in children under 2 years of age, due to the characteristics of their respiratory tract and their limited ability to cough up mucus. Therefore, mucolytics must not be used in children under 2 years of age, see section 4.3.

4.5 Interactions with other medicines and other forms of interaction

Interaction studies have only been performed in adults.

Activated carbon in high doses:

The use of activated charcoal may reduce the effect of acetylcysteine.

Combination with antitussives:

Combined use of ACC 20 mg/ml ORAL SOLUTION with antitussives (cough-relieving agents) may cause a dangerous secretory congestion due to the reduced cough reflex, so that an especially careful diagnosis is required for this combination treatment.

The dissolution of acetylcysteine formulations together with other medicinal products is not recommended.

Antibiotics:

Reports to date on an inactivation of antibiotics (tetracyclines, aminoglycosides, penicillins) due to acetylcysteine exclusively refer to *in vitro* experiments in which the relevant substances were mixed directly. Nevertheless for safety reasons, oral antibiotics should be administered separately and at an interval of at least 2 hours. This does not apply to cefixime and loracarbef.

Acetylcysteine / Glyceryl trinitrate:

The concomitant administration of acetylcysteine can potentially result in an intensification of the vasodilatory and inhibition of platelet aggregation effects of glyceryl trinitrate (nitroglycerine). If a common treatment with nitroglycerin and acetylcysteine is considered necessary, the patient should be monitored for a potential hypotension, which could be serious and may be indicated by headache.

Changes in the determination of laboratory parameters:

Acetylcysteine may affect the colorimetric assay of salicylates.

In urine tests, acetylcysteine may influence the results of determination of ketone bodies.

4.6 Fertility, pregnancy and lactation

Fertility

Data concerning effects of acetylcysteine on human fertility are not available. In animal studies, no harmful effects on fertility were observed for therapy-relevant doses of acetylcysteine.

Pregnancy

There are no adequate clinical data from the use of acetylcysteine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. The use of acetylcysteine during pregnancy is not recommended.

Breastfeeding

No information is available regarding excretion of acetylcysteine or its metabolites into breast milk. A risk for the breast-fed child cannot be excluded. The use of acetylcysteine during breastfeeding is not recommended.

4.7 Effects on ability to drive and use machines

ACC 20 mg/ml ORAL SOLUTION has no known effect on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Less frequent: Hypersensitivity reactions, anaphylactic shock, anaphylactic/anaphylactoid reactions

Nervous system disorders:

Less frequent: Headache

Ear and labyrinth disorders:

***Less frequent*:** Tinnitus

Cardiac disorders:

Less frequent: Tachycardia

Vascular disorders:

Less frequent: Haemorrhage

Respiratory, thoracic and mediastinal disorders:

***Less frequent*:** Dyspnoea, bronchospasm – predominantly in patients with hyper reactive bronchial system in association with bronchial asthma.

Gastrointestinal disorders:

Less frequent: Stomatitis, abdominal pain, nausea, vomiting, diarrhoea and dyspepsia

Skin and subcutaneous tissue disorders:

***Less frequent*:** Stevens-Johnson syndrome and toxic epidermal necrolysis*, urticaria, rash, angioedema, pruritus, exanthema

Investigations:

Less frequent: Hypotension

General disorders and administration site conditions:

***Less frequent*:** Fever

Frequency Unknown: Facial oedema

*In very rare cases, severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in temporal association with the use of acetylcysteine. If skin or mucous membrane abnormalities develop, medical advice should therefore immediately be sought and the use of acetylcysteine discontinued.

A decreased blood platelet aggregation in the presence of acetylcysteine has been confirmed by various studies. The clinical relevance has not yet been clarified to date.

ACC 20 mg/ml ORAL SOLUTION contains methylparahydroxybenzoate. It may cause allergic reactions (possibly delayed).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

4.9 Overdose

Overdoses may lead to gastrointestinal symptoms such as nausea, vomiting and diarrhoea. Infants are at risk of hypersecretion. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cough and cold preparations; mucolytics ATC code: R05C B01

5.1 Pharmacodynamic properties

Mechanism of Action

Acetylcysteine is a mucolytic agent that reduces the viscosity of non-infected bronchial secretions probably by the splitting of disulphide bonds in mucoproteins.

Acetylcysteine is a derivative of the amino acid cysteine. The efficacy of acetylcysteine is secretolytic and secretomotoric in the area of the respiratory tract. It splits off the interconnecting disulphide bonds between the mycopolysaccharide chains and that it has a depolymerizing effect on DNA-chains (in purulent mucus). This leads to a reduction in the viscosity of the mucus.

An alternative mechanism of acetylcysteine is meant to be based on the capacity of its reactive SH group to bind chemical radicals and to detoxify them in this way.

5.2 Phamacokinetic properties

Absorption

Following oral administration, acetylcysteine is rapidly and almost completely absorbed and metabolized in the liver to cysteine, the pharmacologically active metabolite, as well as to diacetylcysteine, cysteine and further mixed disulphides.

Distribution

Due to the high first-pass effect, the bioavailability of orally administered acetylcysteine is very low (approx. 10 %). In humans, maximum plasma concentrations are achieved after 1-3 hours with the maximum plasma concentration of the metabolite cysteine in the range of approx. 2 µmol/l. The protein binding of acetylcysteine was determined to be about 50 %.

Biotransformation

Acetylcysteine and its metabolites occur in three different forms in the body: partially in free form, partially bound to proteins via labile disulphide bonds and partially as incorporated amino acid. Acetylcysteine is excreted almost exclusively in the form of inactive metabolites (inorganic sulphates, diacetylcystine) via the kidneys. The plasma half-life of acetylcysteine is approximately 1 hour and is mainly determined by the rapid hepatic biotransformation. Impaired hepatic function therefore leads to prolonged plasma half-lives of up to 8 hours.

Elimination

Pharmacokinetic studies with intravenous administration of acetylcysteine revealed a distribution volume of 0,47 l/kg (in total) or 0,59 l/kg (reduced); the plasma clearance was determined to be 0,11 l/h/kg (in total) and 0,84 l/h/kg (reduced), respectively. The elimination half-life after intravenous administration is 30-40 minutes while excretion follows three-phase kinetics (alpha, beta and terminal gamma phase).

Acetylcysteine crosses the placenta and is detected in cord blood. No information is available regarding excretion into breast milk.

No knowledge is available concerning the behavior of acetylcysteine at the blood-brain barrier in humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium, cherry flavour (aldehyde C14, alpha-ionone, alpha-tocopherol, anisic aldehyde, benzaldehyde, benzyl acetate, benzyl alcohol, citric acid, dihydro coumarin, ethyl acetate, frambinon® , geranyl butyrate, isoamyl acetate mix, heliotropin/piperonal, maltol, vanillin, propylene glycol-1,2), disodium edetate, methyl parahydroxybenzoate, purified water, saccharin sodium, sodium benzoate, sodium hydroxide 10 % aqueous solution.

Contains sweetener (saccharin sodium 1 mg per ml).

Contains preservatives (methyl parahydroxybenzoate 1,30 mg and sodium benzoate 1,95 mg per ml).

Contains benzyl alcohol, an ingredient of cherry flavour (0,1 mg per ml)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

After first opening the bottle, ACC 20 mg/ml ORAL SOLUTION is stable for 15 days when stored at or below 25 °C.

6.5 Nature and contents of container

The prime container comprises of brown glass bottles with a screw-neck consisting of glass type III. The bottles are sealed with a polypropylene closure system containing an originality (temper evident) ring. The closure system (screw cap) contains a chlorobutyl sealing disk, which is assembled into the cap.

The bottles are equipped with a measuring device in the form of a polypropylene cup allowing withdrawal of 2,5, 5 and 10 ml or a polypropylene-dosing syringe allowing withdrawal of aliquots of up to 5 ml.

Pack sizes of 100 ml and 200 ml bottles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

8 REGISTRATION NUMBER

48/10.3/0261

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 October 2021

10 DATE OF REVISION OF THE TEXT

Not applicable

[1]Company Reg. No.: 1990/001979/07

Additional country registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Botswana	ACC 20 mg / ml oral solution	S3	BOT1402654A/B
Namibia	ACC 20 mg / ml oral solution	NS1	17/10.2.2/0045

ATC Code: R05CB01 – Mucolytics

Name and address of manufacturer:

Pharma Wernigerode,
Dornbersweg 35,
D-38855 Wernigerode,
Germany

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

ACC® 20 mg/ml Oral Solution

Acetylcysteine

Contains sweetener (saccharin sodium 1 mg per ml)

Contains preservatives (methyl parahydroxybenzoate 1,30 mg and sodium benzoate 1,95 mg per ml)

Contains benzyl alcohol, an ingredient of cherry flavour (0,1 mg per ml)

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

ACC 20 mg/ml ORAL SOLUTION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ACC 20 mg/ml ORAL SOLUTION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACC 20 mg/ml ORAL SOLUTION with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within 14 days.

What is in this leaflet

1. What ACC 20 mg/ml ORAL SOLUTION is and what it is used for

ACC 20 mg/ml ORAL SOLUTION contains the active substance Acetylcysteine, which belongs to a group of medicines called mucolytics. Mucolytics work by thinning the mucus and phlegm to help clear

congestion.

2. What you need to know before you take ACC 20 mg/ml ORAL SOLUTION

Do not take ACC 20 mg/ml ORAL SOLUTION if you:

- Are allergic to acetylcysteine, methyl parahydroxybenzoate or to any of the other ingredients of this medicine listed in section 6
- Have a history of stomach ulcers
- If you are pregnant or breastfeeding or suspect that you are pregnant
- ACC 20 mg/ml ORAL SOLUTION must not be used in children of less than 2 years of age.

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

Warnings and precautions

Special care should be taken with ACC 20 mg/ml ORAL SOLUTION:

- ***Skin and mucosal changes***

The occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome has very rarely been reported in connection with the use of acetylcysteine. If skin and mucosal changes newly occur, medical advice should be sought without delay and use of acetylcysteine be terminated.

- ***Gastrointestinal disorders***

Do not take ACC 20 mg/ml ORAL SOLUTION if you have a history of stomach or bowel ulcers or currently have them.

- ***Bronchial asthma***

Do not take ACC 20 mg/ml ORAL SOLUTION if you suffer from asthma, as you may need to be monitored closely whilst taking this medicine.

- ***Hypersensitivity to histamine***

Longer-term therapy should be avoided in these patients, since ACC 20 mg/ml ORAL SOLUTION influences the histamine metabolism and may lead to symptoms of intolerance (e.g. headache, running nose, itching).

- ***Allergic reactions***

ACC 20 mg/ml ORAL SOLUTION contains benzyl alcohol which may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. High volumes should be used with caution and only if necessary, especially if you suffer from liver or kidney disorders due to the risk of harmful effects.

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.

Children

ACC 20 mg/ml ORAL SOLUTION should not be given to children younger than 2 years.

Other medicines and ACC 20 mg/ml ORAL SOLUTION

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. (This includes all complementary or traditional medicines.)

- ***Cough-relieving agents***

Cough suppressants should not be used at the same time as ACC 20 mg/ml ORAL SOLUTION, as you must be able to cough up the loosened phlegm.

- ***Antibiotics***

Experimental studies show evidence of a weakening effect on antibiotics (tetracyclines, aminoglycosides, penicillins) due to acetylcysteine. For safety reasons, antibiotics should be taken separately and at an interval of at least 2 hours. This does not apply to medicines with the active substances cefixime and loracarbef. These may be taken with acetylcysteine at the same time.

- ***Nitroglycerine***

ACC 20 mg/ml ORAL SOLUTION may increase the blood pressure-lowering effect of nitroglycerine [a medicine used against tight painful feeling in the chest (angina pectoris)]. Caution is advised.

- ***Activated Charcoal***

If you use activated charcoal (a medicine against diarrhoea), it may decrease the effect of ACC 20 mg/ml ORAL SOLUTION.

ACC 20 mg/ml ORAL SOLUTION may affect a test for salicylates (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 20 mg/ml ORAL SOLUTION.

Pregnancy and breastfeeding

Safety of ACC 20 mg/ml ORAL SOLUTION 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 this medicine.

- ***Pregnancy***

Use of ACC 20mg/ml ORAL SOLUTION during pregnancy is not recommended.

- ***Breastfeeding***

No information is available regarding excretion of acetylcysteine into breast milk. You should therefore use during breastfeeding only if your doctor deems it absolutely necessary.

Driving and using machines

ACC 20 mg/ml ORAL SOLUTION is not known to influence the ability to drive or operate machines.

ACC 20 mg/ml ORAL SOLUTION contains methyl parahydroxybenzoate

Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

3. How to take ACC 20 mg/ml ORAL SOLUTION

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Please keep the directions for use, otherwise ACC 20 mg/ml ORAL SOLUTION cannot act in the right way.

The recommended dose, if not otherwise prescribed by the doctor, is:

Age	**Total daily dose**
Children aged 2-5 years	5 ml 2-3 times daily
Children and adolescents aged 6-14 years	10 ml 2 times daily
Adults and adolescents aged over 14 years	10 ml 2-3 times daily

10 ml oral solution corresponds to half a measuring cup, or two 5 ml syringe fillings.

Method of use

Take ACC 20 mg/ml ORAL SOLUTION after meals.

ACC 20 mg/ml ORAL SOLUTION is taken by using an oral syringe or the measuring cup enclosed in the pack.

Dosing with the syringe

1. Open the childproof closure of the bottle by pressing the cap down while turning it left.

2. Press the enclosed perforated stopper into the neck of the bottle. If it is not possible to press the stopper completely in, put the closure cap on and turn it. The stopper connects the syringe with the bottle and remains in the neck of the bottle.

3. Firmly put the syringe into the opening of the stopper. The plunger should be in the syringe as far as it will go.

4. Carefully turn the bottle with the syringe upside down. Slowly pull the plunger down until the prescribed number of millilitres (ml) is reached. If you see air bubbles in the solution, repress the plunger into the syringe and refill slowly.
If 10 ml has been prescribed per dose, the syringe must be filled twice.
5. Stand the bottle with the syringe upright again, and pull the syringe out of the perforated stopper.
6. You can administer the solution directly from the syringe into the child's mouth or put it onto a spoon before the child takes it. The child should sit upright when receiving the solution directly into his/her mouth. It is best to empty the syringe towards the inner side of the cheek so that the child does not swallow the wrong way.

Clean the syringe after use by filling and emptying it several times with clear water.

Duration of Use

You must see a doctor if your symptoms worsen or do not improve within 14 days.
If you feel that the effect of ACC 20 mg/ml ORAL SOLUTION is too strong or too weak, please talk to your doctor or pharmacist.

If you take more ACC 20 mg/ml ORAL SOLUTION than you should

In the event of an overdose, irritations in the stomach and bowel tract may occur, such as abdominal pain, nausea, vomiting, diarrhoea.
If an overdose with ACC 20 mg/ml ORAL SOLUTION is suspected, please inform your doctor or visit the nearest clinic.

If you forget to take ACC 20 mg/ml ORAL SOLUTION

Do not use a double dose to make up for a forgotten dose. Just use your next dose at the usual time. If you have any further questions on the use of ACC 20 mg/ml ORAL SOLUTION,

ask your doctor or pharmacist.

4. Possible side effects

ACC 20 mg/ml ORAL SOLUTION can cause side effects, although not everybody gets them.

Stop taking and contact your doctor if signs of an allergic reaction occur.

Consult your doctor if any of the following side effects which may occur less frequently are experienced or bothersome:

- **Allergic reactions,** with signs such as
  - itching, formation of hives, skin rash
  - breathlessness
  - accelerated heartbeat, fall in blood pressure
- **Severe allergic reactions,** up to and including shock
- **Stevens-Johnson Syndrome**

The occurrence of serious skin reactions such as Stevens-Johnson Syndrome and toxic epidermal necrolysis (peeling skin with pain, a flat rash and blisters) have been reported in temporal association with the use of acetylcysteine.

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.

Other possible side effects that may occur less frequently:

- headache

- fever
- inflammation of the inner lining of the mouth
- abdominal pain
- nausea, vomiting
- diarrhoea
- accelerated heart beat
- reduced blood pressure
- itching, formation of hives, skin rash
- generalized rash
- mostly painful, severe swelling of deep skin layers, mainly in the face
- ringing or buzzing in the ears
- bronchospasm – predominantly in patients with hyperreactive bronchial system in the presence of bronchial asthma
- dyspepsia
- bleeding, partially in connection with hypersensitivity reactions

Possible side effects with frequency not known:

- tissue swelling in the face caused by excess fluid
- reduced clumping of blood platelets

Reporting of side effects

If you get side effects, talk to your doctor or 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 20 mg/ml ORAL SOLUTION.

Suspected side effects can also be reported directly to the HCR via

Patientsafety.sacg@novartis.com.

5. How to store ACC 20 mg/ml ORAL SOLUTION

Do not use this medicine after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.

Store at or below 25 °C.

This medicinal product does not require any special storage conditions.

After first opening: Store at or below 25 °C. Use within 15 days.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ACC 20 mg/ml ORAL SOLUTION contains

The active substance is acetylcysteine.

Each 1 ml of oral solution contains 20 mg acetylcysteine.

The other ingredients are carmellose sodium, cherry flavour (aldehyde C14, alpha-ionone, alpha-tocopherol, anisic aldehyde, benzaldehyde, benzyl acetate, benzyl alcohol, citric acid, dihydro coumarin, ethyl acetate, frambinon® , geranyl butyrate, isoamyl acetate mix, heliotropin/piperonal, maltol, vanillin, propylene glycol-1,2), disodium edetate, methyl parahydroxybenzoate, purified water, saccharin sodium, sodium benzoate, sodium hydroxide 10 % aqueous solution.

What ACC 20 mg/ml ORAL SOLUTION looks like and contents of the pack

ACC 20 mg/ml ORAL SOLUTION is a clear, slightly viscous, colourless solution with a cherry flavour in a glass bottle. The prime container comprises of brown glass bottles with a screw-neck consisting of glass type III. The bottles are sealed with a polypropylene closure system

containing an originality (temper evident) ring. The closure system (screw cap) contains a chlorobutyl sealing disk, which is assembled into the cap.

The bottles are equipped with a measuring device in the form of a polypropylene cup allowing withdrawal of 2,5, 5 and 10 ml or a polypropylene dosing syringe allowing withdrawal of aliquots of up to 5 ml.

Pack sizes: 100 ml and 200 ml bottles.
Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]
Waterfall 5-Ir
Magwa Crescent West
Waterfall City
Jukskei View
2090

This leaflet was last revised in

Not applicable

Registration number

48/10.3/0261

[1]Company Reg. No.: 1990/001979/07