**PROFESSIONAL INFORMATION**

**SCHEDULING STATUS:** S1

# 1. NAME OF THE MEDICINE

ACC® 200 (effervescent tablets)

**SANDOZ** A Novartis Division

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ACC 200 effervescent tablet contains: 200 mg acetylcysteine.
Contains sugar (lactose anhydrous 70 mg) and mannitol 60 mg.
Contains sweetener (saccharin sodium 6 mg).

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

ACC 200 effervescent tablets are used as a mucolytic, of non-infective secretions in cystic fibrosis and in respiratory conditions.

### 4.2 Posology and method of administration

**Posology**

***As a mucolytic:***

*Children from 2 to 5 years of age:* ½ (half) an effervescent tablet 2 to 3 times daily (equivalent to 200 to 300 mg acetylcysteine/day).

*Children from 6 to 14 years of age:* 1 effervescent tablet twice daily (equivalent to 400 mg acetylcysteine/day).

*Adults and adolescents from 14 years of age:* 1 effervescent tablet 2 to 3 times daily (equivalent to 400 to 600 mg acetylcysteine/day).

**Method of administration**

The effervescent tablet should be dissolved in a glass of water before use.

**Duration of use**

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

### 4.3 Contraindications

- Hypersensitivity to acetylcysteine or to any of the excipients listed in section 6.1.
- Active peptic ulceration.
- Children below 2 years of age.

Safety in pregnancy has not been established. ACC 200 effervescent tablets should not be used during pregnancy.

### 4.4 Special warnings and precautions for use

Care during use in patients with bronchial asthma and in patients with anamnestic ulcers. If bronchospasm occurs, ACC 200 effervescent tablets should be discontinued immediately and appropriate treatment initiated.

Caution is advised when using this product in patients with a history of ulcers, particularly if additional drugs are being taken that are known to irritate the mucous membranes of the gastrointestinal tract.

The use of ACC 200 effervescent tablets, especially in early treatment can lead to liquefaction and thus to an increase in volume of bronchial secretions. If the patient is unable to expectorate (sufficiently expectorate), appropriate measures (such as drainage and aspiration) should be performed.

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 acetylcysteine. If cutaneous and mucosal changes, newly occur, medical advice should be sought without delay and use of ACC 200 effervescent tablets be terminated (see also section 4.8).

Caution is advised in patients with histamine intolerance. Treatment with ACC 200 effervescent tablets for longer periods should be avoided in such patients, as ACC 200 effervescent tablets affects histamine metabolism and can result in symptoms of intolerance (e.g. headache, runny nose, itching).

**Children and adolescents**

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 Contraindications).

**Important information about some excipients**

ACC 200 effervescent tablets contains lactose anhydrous, which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ACC 200 effervescent tablets.

### 4.5 Interaction with other medicines and other forms of interaction

Combined administration of ACC 200 effervescent tablets with antitussives may cause a dangerous secretory congestion due to the reduced cough reflex, so that an especially careful diagnosis is required for this combination treatment.

Reports to date on an inactivation of antibiotics 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 ACC 200 effervescent tablets can potentially result in an intensification of the vasodilatory and inhibition of platelet aggregation effects of glyceryl trinitrate (nitroglycerine).

If concomitant treatment with glyceryl trinitrate and ACC 200 effervescent tablets is considered necessary, patients should be monitored for the possible development of hypotension, which can be serious, and advised of the possibility of headaches.

Activated carbon in high doses (as an antidote) can reduce the effectiveness of ACC 200 effervescent tablets.

**Changes in the determination of laboratory parameters**

ACC 200 effervescent tablets can affect the colorimetric determination of salicylates.

In urine tests, ACC 200 effervescent tablets can affect the results of determinations of ketone bodies.

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

### 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Safety and/or efficacy has not been established. ACC 200 effervescent tablets should not be used during pregnancy.

**Lactation**

No information is available regarding excretion into breast milk. ACC 200 effervescent tablets should be used during lactation only after strict assessment of the benefit-risk ratio.

**Fertility**

No data are available on the effect of acetylcysteine on human fertility. In animal studies, no adverse effects on fertility were observed at therapeutic doses of acetylcysteine (see section 5.3).

### 4.7 Effects on ability to drive and use machines

Acetylcysteine has no known effect on the ability to drive and use machines.

### 4.8 Undesirable effects

The evaluation of side effects is based on the following information on frequencies:

Frequent: ≥ 1/100.

Less frequent: < 1/10 000 up to < 1/100.

Frequency not known: cannot be estimated from the available data.

**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:*** Nausea, vomiting, diarrhoea, abdominal pain, stomatitis, dyspepsia

**Skin and subcutaneous tissue disorders:**

***Less frequent:*** Urticaria, rash, angioedema, pruritus, exanthema

**General disorders and administration site conditions:**

***Less frequent:*** Fever

***Frequency not known:*** Facial oedema

**Investigations:**

***Less frequent:*** Hypotension

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. In most of these reported cases, at least one additional medicine that could potentially have intensified the described mucocutaneous effects was being taken at the same time.

If skin or mucous membrane abnormalities develop, medical advice should therefore immediately be sought and the use of ACC 200 effervescent tablets discontinued.

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

### 4.9 Overdose

No case of toxic overdose has been observed to date in association with oral pharmaceutical forms of acetylcysteine. Volunteers were treated with a dose of 11,6 g acetylcysteine/day over 3 months without observing any severe side effects. Oral doses up to 500 mg acetylcysteine/kg BW were tolerated without any symptoms of intoxication.

**Symptoms of intoxication**

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

**Therapy of intoxication**

If necessary, according to the symptoms.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A 10.3 Medicines acting on the respiratory system – other

### 5.1 Pharmacodynamic properties

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 is discussed that it splits off the interconnecting disulphide bonds between the mycopolysaccharide chains and that it has a depolymerizing effect on DNA-chains (in purulent mucus). Due to these mechanisms, the viscosity of mucus should be reduced.

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.

Furthermore, acetylcysteine contributes to an increase in glutathione synthesis, which is important for the detoxification of noxae. This provides the explanation for its antidotal effect in paracetamol intoxication.

### 5.2 Pharmacokinetic 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 diacetylcystine, cystine 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 to 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 organism: 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 to 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 behaviour of acetylcysteine at the blood-brain barrier in humans.

### 5.3 Preclinical safety data

**Acute toxicity**

The acute toxicity in animal experiments is low. For the treatment of overdoses, see section 4.9.

**Chronic toxicity**

Studies in various animal species (rat, dog) with a duration of up to one year did not show any pathological alterations.

**Tumorigenic and mutagenic potential**

No mutagenic effects of acetylcysteine are to be expected. An *in vitro* test was negative.

No studies of a tumorigenic potential of acetylcysteine have been carried out.

**Reproductive toxicology**

No malformations were detected in embryotoxicity studies in rabbits and rats. Studies of fertility and perinatal or postnatal toxicity were negative.

Acetylcysteine passes the placenta in rats and was detected in amniotic fluid. The concentration of the metabolite L-cysteine is above the maternal plasma concentration in placenta and foetus for up to 8 hours after oral administration.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

24 months.

### 6.4 Special precautions for storage

Store at or below 25 °C in a cool dry place.

### 6.5 Nature and contents of container

1. Individually sealed laminated aluminium paper foil in an outer cardboard carton.
2. Polypropylene tube with a polyethylene stopper and desiccant in an outer cardboard carton.

Pack sizes of either 20, 25 or 40 effervescent tablets.

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

29/10.2.2/0753

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 November 1996

## 10. DATE OF REVISION OF THE TEXT

08 July 2020

**Additional country registration details:**

| *Country* | *Product name* | *Scheduling status (or Category of distribution)* | *Registration number* |
|---|---|---|---|
| **Namibia** | ACC 200 | NS1 | 04/10.2.2/1307 |
| **Botswana** | ACC 200 | S3 | BOT1202173 |
| **Zambia** | ACC 200 | P | 039/001 |

ATC Code: R05CB01 – Mucolytics

***Name and address of manufacturer:***

Hermes Pharma Ges.m.b.H.
Schwimmschulweg 1a, A-9400 Wolfsberg, Austria
or
Hermes Arzneimittel GmbH
Hans-Urmiller-Ring 52, 82515 Wolfratshausen, Germany
[1]Company Reg. No.: 1990/001979/07

**PATIENT INFORMATION LEAFLET**
**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.
**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[1]
Waterfall 5-Ir, Magwa Crescent West, Waterfall City, Jukskei View, 2090
**This leaflet was last revised in**
08 July 2020
**Registration number**
29/10.2.2/0753
**Access to the corresponding Professional Information**
Not applicable.
[1]Company Reg. No.: 1990/001979/07

V9 (24/08/2020) 7416IB 50089469

**PASIËNTINLIGTINGSPAMFLET**
**SKEDULERINGSTATUS:** [S1]
ACC® 200 (bruistablette)
Asetielsisteien
Bevat suiker [70 mg anhidriese laktose) en 60 mg mannitol
Bevat versoeter (6 mg natriumsakkariien)
**Lees hierdie hele pamflet noukeurig deur voordat jy begin om ACC 200 te neem**
ACC 200 bruistablette is sonder 'n dokter se voorskrif vir jou beskikbaar om 'n matige siekte te behandel. Jy moet ACC 200-bruistablette nogtans versigtig gebruik om die beste resultate daarvan te verkry.
- Hou hierdie pamflet. Dit mag nodig wees dat jy dit weer moet lees.
- Moet nie ACC 200 bruistablette met enigiemand anders deel nie.
- Vra vir jou gesondheidsorgverskaffer of apteker as jy nog inligting of raad nodig het.
- Jy moet 'n dokter raadpleeg as jou simptome vererger of nie binne 14 dae verbeter nie.

**Wat in hierdie pamflet is**
1. Wat ACC 200 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy ACC 200 neem
3. Hoe om ACC 200 te neem
4. Moontlike newe-effekte
5. Hoe om ACC 200 te bewaar
6. Inhoud van die pak en ander inligting

**1. Wat ACC 200 is en waarvoor dit gebruik word**
ACC 200 behoort aan 'n groep mediasyne genaamd mukolitika, wat werk deur die mukus (slym) dun te maak sodat dit makliker uitgehoes kan word.
**2. Wat jy moet weet voordat jy ACC 200 neem**
**Moenie ACC 200 bruistablette neem nie:**
- As jy hipersensitief (allergies) vir asetielsisteien of vir enige van die ander bestanddele van ACC 200 bruistablette is (gelys in afdeling 6).
- As jy 'n geskiedenis van maagsere het.
- As jy swanger is of beplan om swanger te raak. Raadpleeg asseblief jou dokter.
- Moenie ACC 200 bruistablette aan kinders van jonger as 2 jaar oud gee nie.
- Moenie ACC 200 bruistablette vir langer as 14 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.

**Waarskuwings en voorsorgmaatreëls**
***Wees besonders versigtig met ACC 200 bruistablette:***
- As jy asma het.
- As jy 'n geskiedenis van ulkuse het, en veral as jy ander mediasyne neem wat bekend is daarvoor om die voering van die spysverteringskanaal te irriteer.
- As jy histamien nie kan verdra nie. As jy voedsel en drankies wat groot hoeveelhede histamien bevat, nie kan verdra nie, sal ACC 200 moontlik nie vir jou geskik wees nie, want dit beïnvloed hoe histamien in die liggaam afgebreek word. Die mees algemene simptome van histamien-oversdraagsaamheid is hoofpyn, loopneus en jeuk.
- Namate die dik slym meer vloeibaar word, neem die volume daarvan toe, veral aan die begin van die behandeling. As jy nie die vloeibare slym doeltreffend kan ophoes nie, moet jy 'n dokter raadpleeg sodat voldoende maatreëls gerief kan word om die slym te verwyder.
- Daar was seldsame berigte van ernstige hipersensitiwiteitsreaksies met (hoë) koors, rooi vel, gewrigspyne en/of ooginfeksie (Stevens-Johnson-sindroom), en akute hipersensitiwiteitsreaksies wat met koors en blase op die vel of afskilfering van die vel (Lyell-sindroom) gepaardgaan. As jy 'n uitslag of hierdie simptome opdoen, moet jy onmiddellik 'n dokter raadpleeg en ophou om ACC 200 te gebruik.

**Kinders en adolessente**
Moenie by kinders van jonger as 2 jaar oud gebruik nie.
**Ander mediasyne en ACC 200**
Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander mediasyne gebruik. (Dit sluit alle komplementêre of tradisionele mediasyne in.)
Hoesonderdrukkende middels moet nie terseltertyd as ACC 200 bruistablette gebruik word nie, aangesien jy die losgemaakte slym moet kan ophoes.
Moenie ACC 200 bruistablette terseltertyd as enige antibiotika neem nie. Laat 'n interval van minstens twee uur toe tussen die antibiotika en ACC 200 bruistablette. Dit is nie van toepassing op die antibiotika, keftiksien en loracarbef nie.
ACC 200 bruistablette kan die bloeddruk verlagende effek van nitroglisiersalf verhoog ('n mediasyne wat teen stywe, pynlike gevoel in die bors gebruik word [angina pectoris]). Wees versigtig.
As jy geaktiveerde koolstof gebruik ('n mediasyne teen diarreie), kan dit die effek van ACC 200 bruistablette verlaag.
ACC 200 bruistablette kan 'n invloed hê op 'n toets vir salisilaat (soos aspirien) in die bloed. Dit kan ook die uitslae beïnvloed as jy vir ketone in urien toets.
As jy ander mediasyne gebruik, moet jy dit nie saam met ACC 200 bruistablette oplos nie.
**ACC 200 saam met kos, drank en alkohol**
ACC 200 bruistablette moet voor gebruik in 'n glas water opgelos word.
**Swangerskap, borsvoeding en vrugbaarheid**
- Die veiligheid van ACC 200 bruistablette tydens swangerskap en borsvoeding is nie bepaal nie.
- As jy swanger is of borsvoed, dink dat jy dalk swanger kan wees of beplan om 'n baba te hê, moet jy jou dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat jy ACC 200 bruistablette neem.

**Motorbestuur en gebruik van masjinerie**
Geen bekend nie.
**ACC 200 bevat laktose**
ACC 200 bruistablette bevat anhidriese laktose. Pasiënte met die seldsame oorerflike toestande van laktose onverdraagsaamheid moet nie ACC 200 neem nie.
ACC 200 bruistablette bevat anhidriese laktose wat 'n effek op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.
**3. Hoe om ACC 200 te neem**
Moenie mediasyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem ACC 200 bruistablette altyd presies soos wat in hierdie pamflet beskryf word of soos wat jou dokter of apteker vir jou gesê het. Raadpleeg jou dokter of apteker as jy nie seker is nie.
Voordat jy ACC 200 bruistablette neem, moet jy die bruistablet in een glas water oplos en die hele inhoud van die glas drink.
Praat met jou dokter of apteker as jy die indruk kry dat die effek van ACC 200 bruistablette te sterk of te swak is.
Moenie ACC 200 bruistablette vir langer as 14 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.
**Die gewone dosis is:**
***Kinders 2 tot 5 jaar:*** Neem ½ (halwe) ACC 200 bruistablet 2 tot 3 keer per dag.
***Kinders 6 tot 14 jaar:*** Neem een ACC 200 bruistablet twee keer per dag.
***Volwassenes en kinders ouer as 14 jaar:*** Neem een ACC 200 bruistablet 2 tot 3 keer per dag.
**As jy meer ACC 200 geneem het as wat jy moes**
Raadpleeg jou dokter of apteker in geval van oordosering.
As beide nie beskikbaar is nie, kontak die naaste hospitaal of giftebeheersentrum.
Die volgende is alles simptome van 'n oordosis:
- Voel naar of gooi op en diarree.
- Hipersekresie (oormatige produksie van liggaamsafskeidings, soos maagsuur, slym, of sekere hormone) by kinders.

**As jy vergeet om ACC 200 te neem**
As jy vergeet het om 'n dosis te neem, neem dit sodra os wat jy onthou.
Moenie 'n dubbele of groter dosis drink om vir die vergete individuele dosisse op te maak nie.
Gaan voort en drink die volgende dosis op die gewone tyd.
**4. Moontlike newe-effekte**
ACC 200 bruistablette kan newe-effekte hê.
Nie al die newe-effekte wat vir ACC 200 bruistablette aangemeld is, word in hierdie pamflet opgeneem nie.
As jou algemene gesondheidstoestand verslag of as jy enige ongewenste effekte ervaar terwyl jy ACC 200 bruistablette neem, moet jy jou gesondheidsorgverskaffer asseblief om advies raadpleeg.
**As enige van die volgende voorkom, moet jy ophou om ACC 200 bruistablette te neem en dadelik vir jou dokter sê of na die ongevalle-afdeling van jou naaste hospitaal gaan:**
- Allergiese reaksie met swelling van die gesig, lippe, mond, tong of keel wat probleme met sluk of asemhaling, uitslag of jeuk kan veroorsaak.
- Daar was seldsame berigte van ernstige hipersensitiwiteitsreaksies met (hoë) koors, rooi vel, gewrigspyne en/of ooginfeksie (Stevens-Johnson-sindroom), en akute hipersensitiwiteitsreaksies wat met koors en blase op die vel of afskilfering van die vel (Lyell-sindroom) gepaardgaan.

Dit is alles baie ernstige newe-effekte. As jy dit ervaar, kan dit wees dat jy 'n ernstige allergiese reaksie teenoor ACC 200 bruistablette gehad het. Dit mag wees dat jy dringende mediese aandag of hospitalisasie nodig het.
**Sê dadelik vir jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal as jy enige van die volgende opmerk:**
- Veranderinge in die manier waarop jou hart klop, as jy bywoorbeeld opmerk dat dit vinniger klop.
- Lae bloeddruk.
- Moeilike asemhaling of vinnige asemhaling.

Die bogenoemde is alles ernstige newe-effekte. Dit mag wees dat jy dringende mediese aandag nodig het.
**Sê vir jou dokter as jy enige van die volgende opmerk:**
***Newe-effekte wat minder dikwels voorkom:***
- Hoofpyn
- Gegoes, gesis, gefluit, geluid of ander aanhoudende geraas in die ore
- Bloeding
- Maagpyn
- Sere in jou mond
- Diarree
- Braking
- Sooibrand
- Slegte spysvertering
- Naarheid
- Veluitslag, jeuk of galbulte
- Koors

***Die frekwensie van die volgende newe-effekte is onbekend:***
- Swelling in die gesig

Verskillende studies het bevind dat die aktiewe komponent in ACC 200, asetielsisteien, die vermoë van jou bloed om te stol kan verminder.
As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet jy jou dokter of apteker asseblief in kennis stel.
**Aanmelding van newe-effekte**
Praat met jou dokter, apteker of verpleegkundige as jy newe-effekte kry. Jy kan newe-effekte ook by SAHPRA aanmeld met die toepaslike vorm, naamlik "**6.04 Adverse Drug Reaction Reporting Form**" wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van ACC 200 te gee.
Vermeende newe-effekte kan ook direk aan die houer van die registrasiesertifikaat aangemeld word by
Patientsafety.sacg@novartis.com.
**5. Hoe om ACC 200 te bewaar**
- Bewaar teen of onder 25 °C op 'n koel droë plek.
- **BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS**
- Moenie die tablette gebruik na die vervaldatum wat op die houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Ongebruikte medisyne moet nie in dreine en rioolstelsels (bv. toilette) weggegooi word nie.

**6. Inhoud van die pak en ander inligting**
**Wat ACC 200 bruistablette bevat**
***Aktiewe bestanddeel:***
Elke ACC 200 bruistablet bevat 200 mg asetielsisteien.
***Onaktiewe bestanddele:***
Askorbiensuur, swartbesie geur "B", anhidriese sitroensuur, anhidriese laktose, mannitol, natriumwaterstofkarbonaat, anhidriese natriumkarbonaat, natriumsitraat en natriumsakkariien.
**Hoe ACC 200 lyk en die inhoud van die pak**
ACC 200 is wit ronde tablette, vlekkeloos, met 'n breeklyn aan die een kant (200 mg) en die reuk van swartbesies.
ACC 200 is verpak in:
- Plastiekbuise met 'n prop in 'n buitenste kartonhouer.
- Individuel verseëlde gelamineerde aluminiumpapierbeile in 'n buitenste kartonhouer.

Let wel: pakgroottes van of 20, 25 of 40 bruistablette.
Nie alle pakgroottes word noodwendig bemark nie.
**Houer van die Sertifikaat van Registrasie**
Sandoz SA [Edms] Bpk[1]
Waterfall 5-Ir, Magwasingel Wes, Waterfall City, Jukskei View 2090
**Hierdie pamflet is laas hersien in**
08 Julie 2020
**Registrasienommer**
29/10.2.2/0753
**Toegang tot die toepaslike Professionele Inligting**
Nie van toepassing nie.
[1]Maatskappy Reg. Nr.: 1990/001979/07

V9 (24/08/2020) 7416IB 50089469