PROFESSIONAL INFORMATION

SCHEDULING STATUS: S1

1. NAME OF THE MEDICINE

ACC® 600 (effervescent tablets)

ACC® 600 ORAL POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACC 600 (effervescent tablets):

Each effervescent tablet contains 600 mg acetylcysteine.

Excipients with known effects:

Contains sugar: lactose anhydrous (70 mg per tablet).

Contains sweetener: mannitol (72,80 mg per tablet), saccharin sodium (5 mg per tablet), sodium cyclamate (30,75 mg per tablet) and sorbitol (an ingredient of the flavour blackberry “B”).

ACC 600 ORAL POWDER:

Each sachet contains 600 mg of acetylcysteine.

Excipients with known effects:

Contains sweetener: aspartame (0,50 mg per sachet), sorbitol (approximately 526,50 mg per sachet) and xylitol (200 mg per sachet), mannitol (an ingredient of the flavour blackberry “B”).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

ACC 600 (effervescent tablets):

White, round tablets, scored on one side, faultless surface and a smell of blackberries.

When an ACC 600 effervescent tablet is dissolved in a glass of water, the appearance of the solution is clear, colourless, with no particles and a smell of blackberries.

ACC 600 ORAL POWDER:

Oral powder in sachet.

White to slightly yellowish powder, easily disaggregating agglomerates if any, with an odour of blackberry, possibly slightly sulphuric.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ACC 600 oral powder or effervescent tablets are used as a mucolytic in acute respiratory conditions.

4.2 Posology and method of administration

Posology:

ACC 600 (effervescent tablets):

Adults and adolescents from 14 years of age:

½ effervescent tablet twice daily or 1 effervescent tablet once daily (equivalent to 600 mg acetylcysteine per day).

ACC 600 ORAL POWDER:

For adults only:

1 sachet once daily (equivalent to 600 mg acetylcysteine per day).

ACC 600 ORAL POWDER is not suitable for use in adolescents and children.

Method of administration:

ACC 600 (effervescent tablets):

The effervescent tablets are taken dissolved in a glass of water after meals.

Duration of use:

ACC 600 effervescent tablets should not be taken for more than 14 days without medical advice.

ACC 600 ORAL POWDER:

The oral powder of one sachet should be placed directly on the tongue. The oral powder stimulates salivation so the oral powder can be swallowed easily. The oral powder should not be chewed before swallowing. Can be taken without water.

Elderly and weakened patients:

Patients with a reduced cough reflex (elderly and weakened patients) should take the oral powder preferably in the morning.

Duration of use:

ACC 600 ORAL POWDER should not be taken for more than 14 days without medical advice.

Paediatric patients:

Due to the high content of active substance, acetylcysteine 600 mg should not be used in children less than 14 years of age.

4.3. Contraindications

Hypersensitivity to acetylcysteine and/or any of the other ingredients of ACC 600.

Safety in pregnancy has not been established. ACC 600 should not be used during pregnancy (see section 4.6).

Active peptic ulceration.

4.4. Special warnings and precautions for use

ACC 600 should be used with caution in asthmatic patients. If bronchospasm occurs, the use of acetylcysteine must be stopped immediately and appropriate treatment initiated.

ACC 600 should be used with caution in patients with a history of peptic ulcer disease, both because drug-induced nausea and vomiting may increase the risk of gastrointestinal haemorrhage in patients predisposed to the condition, and because of a theoretical risk that mucolytics may disrupt the gastric mucosal barrier.

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 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 occur, consult your health care provider without delay and use of acetylcysteine be terminated (see section 4.8).

Intolerance:

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

ACC 600 effervescent tablets contains lactose anhydrous.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take ACC 600 effervescent tablets.

ACC 600 effervescent tablets contains lactose anhydrous, which may have an effect on the glycaemic control of patients with diabetes mellitus.

ACC 600 ORAL POWDER contains aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

4.5. Interaction with other medicines and other forms of interaction

Combined administration of ACC 600 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.

Tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics must be administered separately from ACC 600 and with an interval of at least 2 hours.

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 concomitant treatment with glyceryl trinitrate and acetylcysteine 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 charcoal in high doses (as an antidote) can reduce the effectiveness of acetylcysteine.

Acetylcysteine can affect the colorimetric determination of salicylates.
In urine tests, acetylcysteine can affect the results of determinations of ketone bodies.
The dissolution of ACC 600 together with other medicines is not recommended.

4.6 Fertility, pregnancy and lactation

Safety and efficacy of acetylcysteine in pregnancy and lactation have not been established (see section 4.3).

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. ACC 600 should not be used during pregnancy.

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

4.8. Undesirable effects

Immune system disorders:

Less frequent: Hypersensitivity reactions.

Frequency unknown: Anaphylactic shock, anaphylactic / anaphylactoid reactions.

Nervous system disorders:

Less frequent: Headache, convulsions, syncope.

Eye disorders:

Less frequent: Blurred vision.

Ear and labyrinth disorders:

Less frequent: Tinnitus.

Cardiac disorders:

Less frequent: Tachycardia.

Vascular disorders:

Less frequent: Haemorrhage, hypertension.

Respiratory, thoracic and mediastinal disorders:

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

Gastrointestinal disorders:

Less frequent: Nausea, vomiting, diarrhoea, abdominal pain, stomatitis.

Frequency unknown: Dyspepsia.

Hepato-biliary disorders:

Less frequent: Disturbances of the liver function, acidosis.

Skin and subcutaneous tissue disorders:

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

Musculoskeletal, connective tissue and bone disorders:

Less frequent: Arthralgia.

General disorders and administration site conditions:

Less frequent: Fever, hypotension.

Frequency unknown: Facial oedema.

*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, the use of acetylcysteine must be discontinued immediately.

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.

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 of overdose is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Cough and cold preparations;

Mucolytics

ATC Code: R05CB01

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 depolymerising 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. Pharmacokinetic properties

Absorption:

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

Distribution:

Due to the high first-pass effect, the bioavailability of orally administered acetylcysteine is very low (approx. 10 %). Maximum plasma concentrations are achieved after 1 to 3 hours. The protein binding of acetylcysteine is approximately 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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

ACC 600 (effervescent tablets):

Ascorbic acid

Blackberry flavour “B” (gluconolactone (E575), maltodextrin, magnesium carbonate (E504 II), mannitol (E421), natural / nature identical liquid flavour, type “wildberry”, code no. 5752, nature identical liquid flavour, type “blackberry”, code no. 5337, silica, colloidal anhydrous (E551), sorbitol (E420), vanillin)

Citric acid anhydrous

Lactose anhydrous

Mannitol

Saccharin sodium

Sodium carbonate anhydrous

Sodium citrate 2 H_2O

Sodium cyclamate

Sodium hydrogen carbonate

ACC 600 ORAL POWDER:

Aspartame

Carmellose sodium

Citric acid anhydrous

Flavour blackberry “B” (colloidal anhydrous silica, gluconolactone, magnesium carbonate, maltodextrin, mannitol, natural / nature identical liquid flavour, type “wildberry”, code no. 5752, nature identical liquid flavour, type “blackberry”, code no. 5337, sorbitol, vanillin)

Glyceryl tripalmitate

Magnesium citrate

Magnesium stearate

Monosodium citrate

Polysorbate 65

Sorbitol

Xylitol

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

ACC® 600 (effervescent tablets): 36 months

In use shelf life after first opening: 24 months

ACC® 600 ORAL POWDER: 24 months

6.4. Special precautions for storage

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

Protect from light.

Keep the tubes tightly closed in order to protect from moisture.

Keep the sachet in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

ACC 600 (effervescent tablets):

Polypropylene tubes containing 10, 20, 25, or 40 effervescent tablets, closed with polyethylene stoppers containing desiccant and packed into a cardboard box together with the leaflet.

Alternatively, the effervescent tablets are sealed individually in laminated aluminium-paper-foil sachets.

10, 20, 25 or 40 sachets are packed into a cardboard box together with the leaflet.

ACC 600 ORAL POWDER:

ACC ORAL POWDER is filled into laminated aluminium-paper-foil sachets and sealed.

The sachets are packed together with the leaflet into paper folded card boxes.

The sachets are available in pack sizes of 8, 10, 14, 20, 30, 60 or 90.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

8. REGISTRATION NUMBERS

ACC 600 (effervescent tablets): 45/10.3/0229

ACC 600 ORAL POWDER: 51/10.3/0816

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

ACC 600 (effervescent tablets): 02 November 2021

ACC 600 ORAL POWDER: 26 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 600	S3	BOT1702941/A/B

ATC Code: R05CB01 – Mucolytics

Name and address of manufacturer:

Hermes Pharma GmbH

Hans-Urmiller-Ring 52
82515 Wolfratshausen
Germany

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

ACC® 600 (effervescent tablets)

ACC® 600 ORAL POWDER

Acetylcysteine

ACC 600 (effervescent tablets) contains sugar: lactose anhydrous (70 mg per tablet).

ACC 600 (effervescent tablets) contains sweetener: mannitol (72,80 mg per tablet), saccharin sodium (5 mg per tablet), sodium cyclamate (30,75 mg per tablet) and sorbitol (an ingredient of the flavour blackberry “B”).

ACC 600 ORAL POWDER contains sweetener aspartame (0,50 mg per sachet), sorbitol (approximately 526,50 mg per sachet) and xylitol (200 mg per sachet).

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

ACC 600 is available without a doctor’s prescription, for you to treat a mild illness. Nevertheless, you still need to use ACC 600 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACC 600 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 600 is and what it is used for

- ACC 600 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 600

Do not take ACC 600 if:

- If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of ACC 600 (listed in section 6).
- If you have a history of stomach ulcers.
- If you are pregnant or plan to become pregnant (see “Pregnancy and breastfeeding”). Please consult with your doctor.
- Do not give ACC 600 effervescent tablets to children less than 14 years of age.
- ACC 600 ORAL POWDER is for adult use only.

Warnings and precautions

Take special care with ACC 600:

- If you have asthma.
- If you have or have a history of stomach ulcers.
- 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.

- If you have a skin condition called Stevens-Johnson syndrome or Lyell's syndrome, which is characterised by severe blisters and bleeding in the lips, eyes, mouth, nose and genitals or fever, chills, aching muscles and generally feeling unwell.
- If you are intolerant to histamines. If you are not able to tolerate food and drinks that contain large amounts of histamines, ACC 600 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.

Other medicines and ACC 600

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:

- Cough relieving medicines (cough suppressant medicines).
- Antibiotics such as tetracyclines used to treat bacterial infections; these medicines should be taken 2 hours apart.
- 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).
- Activated charcoal.

ACC 600 with food and drink

ACC 600 effervescent tablets should be taken dissolved in a glass of water after food.

ACC 600 ORAL POWDER can be taken without water.

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 600.

Use of ACC 600 during pregnancy is not recommended.

Driving and using machines

It is not always possible to predict to what extent ACC 600 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 600 affects them.

ACC 600 effervescent contains:

ACC 600 effervescent tablets and ACC 600 ORAL POWDER contains mannitol and sorbitol. If you have been told that you have an intolerance to some sugars, you should not take ACC 600.

ACC 600 effervescent contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ACC 600.
ACC 600 effervescent tablets contains lactose anhydrous, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

ACC 600 ORAL POWDER contains:

Aspartame, which is a source of phenylalanine, and can be harmful for patients with phenylketonuria.

3. How to take ACC 600

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

Always take ACC 600 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.

ACC 600 (effervescent tablets):

Adults and adolescents from 14 years of age:

The usual dose is ½ an effervescent tablet twice daily or 1 effervescent tablet once daily (equivalent to 600 mg acetylcysteine per day).

The effervescent tablets must be taken with a glass of water after food.

Do not give ACC 600 effervescent tablets to children less than 14 years of age.

ACC 600 ORAL POWDER:

For adults only:

The usual dose of one sachet (600 mg) should be placed directly on the tongue.

The oral powder of one sachet should be placed directly on the tongue. The oral powder stimulates salivation so the oral powder can be swallowed easily. The oral powder should not be chewed before swallowing.

Elderly and weakened patients:

Patients with a reduced cough reflex (elderly and weakened patients) should take the oral powder preferably in the morning.

ACC 600 should not be taken for more than 14 days without medical advice.

If you take more ACC 600 than you should

Overdoses with ACC 600 may include irritations in the stomach and bowel tract, such as abdominal pain, nausea, vomiting, diarrhoea.

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

If you forget to take ACC 600

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

4. Possible side effects

ACC 600 can have side effects.

Not all side effects reported for ACC 600 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACC 600, please consult your health care provider for advice.

If any of the following happens, stop taking ACC 600 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.
- Seizures (fits).
- Fainting.
- Stevens-Johnson syndrome (rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals),
- Toxic epidermal necrolysis (severe skin reactions that starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell).

These are all very serious side effects. If you have them, you may have had a serious reaction to ACC 600. 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:

- Difficulty breathing.
- Changes in the way your heart beats, for example, if you notice it beating faster.
- Yellowing of the skin and eyes, dark urine, and tiredness, which may be symptoms of liver problems.

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,
- Blurred vision,
- Ringing in the ear,
- Bleeding,
- High blood pressure,
- Nausea,
- Vomiting,
- Diarrhoea,
- Stomach pain,
- Mouth ulcers and cold sores,
- High level of acid in the body,
- Skin rash,
- Swelling,
- Itching,
- Flushing,

- Painful, swollen joints,
- Fever,
- Low blood pressure.

Frequency unknown side effects:

- Indigestion,
- 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 or pharmacist. 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 600.

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

5. How to store ACC 600

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C in a cool dry place.
- Do not use ACC 600 after the expiry date, which is stated on the carton after Exp. The expiry date refers to the last day of that month.
- Keep the tubes tightly closed in order to protect from moisture.
- Keep the sachet in the carton until required for use.
- Protect from light.

6. Contents of the pack and other information

What ACC 600 (effervescent tablets) contains

The active substance is acetylcysteine.

The other ingredients are ascorbic acid, blackberry flavour “B” (gluconolactone (E575), maltodextrin, magnesium carbonate (E504 II), mannitol (E421), natural/nature identical liquid flavour, type “wildberry”, code no. 5752, nature identical liquid flavour, type “blackberry”, code no. 5337, silica, colloidal anhydrous (E551), sorbitol (E420), vanillin), citric acid anhydrous, lactose anhydrous, mannitol, saccharin sodium, sodium carbonate anhydrous, sodium citrate 2 H_2O, sodium cyclamate, sodium hydrogen carbonate.

What ACC 600 ORAL POWDER contains

The active substance is acetylcysteine.

The other ingredients are aspartame, carmellose sodium, citric acid anhydrous, flavour blackberry “B” (colloidal anhydrous silica, gluconolactone, magnesium carbonate, maltodextrin, mannitol, natural/nature identical liquid flavour, type “wildberry”, code no. 5752, nature identical liquid flavour, type “blackberry”, code no. 5337, sorbitol, vanillin), glyceryl tripalmitate, magnesium citrate, magnesium stearate, monosodium citrate, polysorbate 65, sorbitol, xylitol.

What ACC 600 looks like and contents of the pack

ACC 600 (effervescent tablets):

ACC 600 is white, round effervescent tablets scored on one side, faultless surface and a smell of blackberries.

When an ACC 600 effervescent tablet is dissolved in a glass of water, the appearance of the solution is clear, colourless, with no particles and a smell of blackberries.

ACC 600 is packed in polypropylene tubes containing 10, 20, 25 or 40 effervescent tablets, closed with polyethylene stoppers containing desiccant and packed into a cardboard box together with the leaflet.

Alternatively, the effervescent tablets are sealed individually in laminated aluminium-paper-foil sachets.

10, 20, 25 or 40 sachets are packed into a cardboard box together with the leaflet.

ACC 600 ORAL POWDER:

White to slightly yellowish powder, easily disaggregating agglomerates if any, with an odour of blackberry, possibly slightly sulphuric.

ACC ORAL POWDER is filled into laminated aluminium-paper-foil sachets and sealed.

The sachets are packed together with the leaflet into paper folded card boxes.

The sachets are available in pack sizes of 8, 10, 14, 20, 30, 60 or 90.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

This leaflet was last revised in

Not applicable

Registration numbers

ACC 600: 45/10.3/0229

ACC 600 ORAL POWDER: 51/10.3/0816

Access to the corresponding Professional Information

Not applicable

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