PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

ACEFizz 200

ACEFizz 600

Effervescent tablets containing acetylcysteine 200 or 600 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

ACEFizz 200:	Acetylcysteine	200 mg
ACEFizz 600:	Acetylcysteine	600 mg

Contains sugar:

ACEFizz 200: 375 mg sorbitol.

ACEFizz 600: 160 mg sorbitol.

Contains sweeteners:

ACEFizz 200: 10 mg aspartame and 10 mg saccharin sodium.

ACEFizz 600: 10 mg aspartame and 5 mg saccharin sodium.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Effervescent tablets.

Off-white to light-yellow, round, flat effervescent tablets with a mild sulphur odour. Upon dissolution in water, it is a light-yellow fizzy solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Promotes overall physical well-being.

- Supplementation of the dietary supply of amino acids used for the synthesis of body protein and other nitrogen-containing compounds.
- Amino acids serve many functions to create optimal health.
- Source of an amino acid involved in muscle protein synthesis (N-acetyl-L-cysteine as a source of L-cysteine).

4.2. Posology and method of administration

Take a few hours before or after taking other medications or natural health products.

Adults: Dissolve 1 (one) effervescent tablet in half a glass of water:
ACEFizz 200: three times a day
ACEFizz 600: once daily (preferably in the mornings)
Take with food.
The indicated daily dose should not be exceeded.
Do not use ACEFizz continuously for more than 14 days without consulting a doctor or pharmacist.

Paediatric population

ACEFizz should not be used in children or adolescents under the age of 18 years.

4.3. Contraindications

- Hypersensitivity/allergy to acetylcysteine or any of the other ingredients.
- Pregnancy and lactation.
- In children and adolescents.

4.4. Special warnings and precautions for use

Health supplements are intended only to complement health or supplement the diet.

- Bronchospasms may occur with the use of acetylcysteine. If bronchospasm occurs, the medicinal product should be discontinued immediately.
- Bronchial secretions may become more fluid and increase in volume, particularly during in the initial stages of supplementation with acetylcysteine.
- Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have been reported whilst taking acetylcysteine, but these occur rarely (see section 4.8). For this reason, medical advice should be sought immediately, and the patient should stop taking acetylcysteine in the event of new-onset changes to the skin and mucous membranes.
- This product should be used with caution by patients with histamine intolerance. They should avoid long-term therapy because acetylcysteine effervescent tablet affects the metabolism of histamine and can lead to symptoms of intolerance (e.g. headaches, rhinitis, itching).
- No specific studies have been performed in patients with renal or hepatic impairment. Hepatic and renal impairment reduce clearance and increase acetylcysteine plasma levels which may result in an increase in adverse drug reactions due to drug accumulation. Use with caution in patient with hepatic and renal impairment.

- Contains sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.
- 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.
- Contains sodium. Caution is advised in patients on a sodium-restricted diet.
  ACEFizz 200 mg: This medicinal product contains 81,41 mg sodium per effervescent tablet (244,23 mg sodium per day), equivalent to 12 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
  ACEFizz 600 mg: This medicinal product contains 172,66 mg sodium per effervescent tablet, equivalent to 9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- The indicated daily dose should not be exceeded.
- Do not use ACEFizz continuously for more than 14 days without consulting a doctor or pharmacist.

Asthmatic patients

ACEFizz should be used with caution in patients with asthma.

Elderly patients

ACEFizz should be used with caution in elderly patients with impaired respiratory function.

History of peptic ulceration

ACEFizz should be used with caution in patients with a history of ulcers as the gastric mucosal barrier may be disrupted.

4.5. Interaction with other medicines and other forms of interaction

- Simultaneous use with ACEFizz may decrease absorption of tetracyclines and other oral antibiotics. Administer separately from ACEFizz at least 2 hours before or after.
- Acetylcysteine interference with laboratory tests – ACEFizz may influence the values of salicylates by colorimetric analysis and may interfere with tests for ketones in urine.
- Concurrent administration of nitroglycerin with acetylcysteine causes significant hypotension and leads to temporal artery dilation, which may result in a headache. If concurrent administration is required with ACEFizz, patients should be cautioned about severe hypotension and headache and should be appropriately monitored.
- ACEFizz should not be administered concurrently with antitussive (cough suppressant) medicinal products because it reduces the cough reflex and may lead to a build-up of bronchial secretions.

- Activated charcoal can decrease the effect of ACEFizz due to reduced absorption.

4.6. Fertility, pregnancy and lactation

The safety and/or efficacy of acetylcysteine during pregnancy and breastfeeding has not been established, and there is no available data on fertility, therefore the use of ACEFizz is contraindicated (see section 4.3).
It is not known if acetylcysteine excretes in breastmilk.

4.7. Effects on ability to drive and use machines

ACEFizz has no known effect on the ability to drive and use machines. No studies have been performed. ACEFizz does not cause drowsiness, however, as with any new medicine, care should be taken while driving or using machinery (see section 4.8).

4.8. Undesirable effects

Serious skin reactions such as Stevens-Johnson syndrome and Toxic Epidermal Necrolysis, TEN (Lyell's syndrome) have rarely been reported, and was mostly reported when another medicine was concurrently administered which possibly enhanced the effects (see section 4.4).

Immune system disorders

Less frequent

Hypersensitivity (anaphylactoid reaction, anaphylactic shock)

Nervous system disorders

Less frequent

Headache

Frequency not known

Convulsions

Eye disorders

Frequency not known

Blurred vision

Cardiac disorders

Frequency not known

Cardiac arrest

Vascular disorders

Less frequent

Hypotension, occasional hypertension

Frequency not known
Flushing, syncope and sweating

Respiratory, thoracic and mediastinal disorders
Less frequent
Bronchospasm (predominantly in patients with hyper reactive bronchial system in association with bronchial asthma) and rhinorrhoea

Frequency not known
Respiratory arrest and haemoptysis

Gastrointestinal disorders
Less frequent
Stomatitis, nausea, vomiting
ACEFizz should be used with caution in patients with recent gastro-duodenal ulceration (see section 4.4)

Hepato-biliary disorders
Frequency not known
Disturbances of liver function

Skin and subcutaneous tissue disorders
Less frequent
Angioedema and pruritus, rashes

Rare
Stevens-Johnson syndrome and Toxic Epidermal Necrolysis, TEN (Lyell's syndrome)

Musculoskeletal, connective tissue and bone disorders
Frequency not known
Arthralgia

General disorders and administration site conditions
Less frequent
Fever chills

Frequency not known
Acidosis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (**Medsafety X SAHPRA**) and eReporting platform (**who-umc.org**) found on SAHPRA website.

Adverse reactions must also be reported to MC Pharma (Pty) Ltd at pv@mcpharma.co.za / 012 668 3019.

4.9. Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). To date no toxic overdose has been observed for the oral pharmaceutical forms of acetylcysteine.

Symptoms

Overdoses may lead to gastrointestinal effects such as nausea, vomiting and diarrhoea.

Management

Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological action

Non-essential amino acids such as acetylcysteine (also called N-acetyl-L-cysteine) are those that can be synthesised by the body. These non-essential amino acids serve many functions to create optimal health.

5.1. Pharmacodynamic properties

Category D: Complementary Medicine - Health Supplement

Class 34.1 Amino acids

Acetylcysteine belongs to the group of amino acid cysteine derivative.

5.2. Pharmacokinetic properties

Absorption and metabolism

Acetylcysteine is absorbed rapidly and almost completely after oral administration. It is metabolized in the liver into a pharmaceutically active metabolite cysteine, inactive diacetylcystine and cystine and into the other disulfides. Due to the high first pass effect, the bioavailability of orally administered acetylcysteine is very low (approximately 10 %).

In humans, peak plasma concentrations occur about 0.5 to 1 hour after oral doses of 200 to 600 mg Acetylcysteine. These concentrations may be present in plasma as the parent

compound or as various oxidised metabolites either free or bound to plasma proteins by labile disulfide bonds. Protein binding is about 50 % four hours after administration.

Elimination
30 % Acetylcysteine is excreted as inactive metabolites (inorganic sulfates, diacetylcystine) through the renal route. The terminal half-life of total acetylcysteine is about 6.25 hours after oral doses. In patients with liver dysfunction the elimination half-life of acetylcysteine increases to 8 hours.

Distribution
In a study with rats it was shown that acetylcysteine crosses the placenta.
There is no information on whether acetylcysteine crosses the blood-brain barrier in humans. There are no data on whether acetylcysteine is excreted in breast milk.

Hepatic and renal impairment
There is evidence that clearance of acetylcysteine can be significantly reduced up to 90 % in the subjects with end-stage renal disease. This could result in a marked increase in systemic exposure to acetylcysteine in the extreme case of patients with end-stage renal disease. It is not known to what extent the results can be extrapolated to the less severe forms of renal impairment that are more likely to be encountered during routine use of proposed product. The elimination half-life of acetylcysteine was found to increase to eight hours in one study of patients with chronic liver disease. The total clearance of acetylcysteine was found to be significantly reduced following an intravenous dose of 600 mg over three minutes in nine subjects with hepatic cirrhosis.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Citric acid, sodium hydrogen carbonate, sorbitol, sodium carbonate, sodium benzoate, macrogol, copovidone, aspartame, saccharin sodium, orange flavours, betacarotene 1 % and ascorbic acid.

6.2. Incompatibilities
Not applicable.

6.3. Shelf life
3 years.

6.4. Special precautions for storage
Keep out of the reach of children.
Store at or below 30 ˚C.

Keep the container tightly closed. Protect from light and moisture.
Keep tablets in the original packaging until required for use.
Do not use after the expiry date printed on the packaging.

6.5. Nature and contents of container

Alu-Alu blisters in a carton box, containing 10, 16 or 20 effervescent tablets.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. APPLICANT

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pharmacist@mcpharma.co.za
www.mcpharma.co.za

8. REGISTRATION NUMBER

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

9. DATE OF FIRST AUTHORISATION

July 2026

10. DATE OF REVISION OF THE TEXT