PROPOSED PATIENT INFORMATION LEAFLET FOR ACTEFF 600

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

ACTEFF 600 effervescent tablets

Acetylcysteine

ACTEFF 600 is sugar free

Contains sweetener (sucralose, 10 mg per effervescent tablet)

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

ACTEFF 600 is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ACTEFF 600 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTEFF 600 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 ACTEFF 600 is and what it is used for
2. What you need to know before you take ACTEFF 600
3. How to take ACTEFF 600
4. Possible side effects
5. How to store ACTEFF 600
6. Contents of the pack and other information

1. What ACTEFF 600 is and what it is used for

- ACTEFF 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 ACTEFF 600

Do not take ACTEFF 600:

- If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of ACTEFF 600 (listed in section 6).
- If you have stomach ulcers.
- If you are pregnant or plan to become pregnant (see "**Pregnancy, breastfeeding and fertility**"). Please consult with your doctor.

Warnings and precautions

Take special care with ACTEFF 600:

- If you suffer from 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 develop 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, stop taking ACTEFF 600 and tell your doctor immediately.
- If you are intolerant to histamines. If you are not able to tolerate food and drinks that contain large amounts of histamines, ACTEFF 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.

Children and adolescents

ACTEFF 600 is not suitable for use in children under the age of 14 (see "**Do not take**

ACTEFF 600").

Other medicines and ACTEFF 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; ACTEFF 600 and these medicines should be taken 2 hours apart.
- Glyceryl trinitrate (nitroglycerine) used for heart failure, high blood pressure and to treat and prevent chest pain due to not enough blood flow to the heart (angina).
- Activated charcoal.

ACTEFF 600 with food and drink

ACTEFF 600 should be dissolved in a glass of water and taken after meals.

Pregnancy, breastfeeding and fertility

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 ACTEFF 600.

The use of ACTEFF 600 during pregnancy is contraindicated (see Do not take ACTEFF 600).

Use of ACTEFF 600 during breastfeeding is not recommended.

Driving and using machines

There are no data available on the effect of ACTEFF 600 on the ability to drive or use machines. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACTEFF 600 affects them.

ACTEFF 600 contains salt (sodium)

ACTEFF 600 contains 115 mg sodium (main component of cooking/table salt) per effervescent tablet. This is equivalent to 5,75 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take ACTEFF 600

Do not share ACTEFF 600 with any other person.

Always take ACTEFF 600 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.

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 dissolved in a glass of water after food.

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

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

If you have the impression that the effect of ACTEFF 600 is too strong or too weak, tell your doctor or pharmacist.

If you take more ACTEFF 600 than you should

Overdoses with ACTEFF 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 ACTEFF 600:

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

4. Possible side effects

ACTEFF 600 can have side effects.

Not all side effects reported for ACTEFF 600 are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking ACTEFF 600, please consult your health care provider for advice.

If any of the following happens, stop taking ACTEFF 600 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting.

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

- 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),
- 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 as soon as possible if you notice any of the following:

Less frequent side effects:

- Headache, convulsions, fainting,
- Blurred vision,
- Ringing or buzzing in the ears,
- General bleeding, high blood pressure,
- Nausea (feeling sick), vomiting (being sick), 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.

Side effects of unknown frequency:

- 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 ACTEFF 600.

5. How to store ACTEFF 600

- Store at or below 25 °C.
- Store in the original container, protected from moisture and light.
- It is recommended that ACTEFF 600 is used within 90 days after opening.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.

- Do not use after the expiry date printed on the carton.
- 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 ACTEFF 600 contains:

The active substance is acetylcysteine, 600 mg.

The other ingredients are citric acid, orange flavour (containing butylated hydroxyl anisole, citric acid, gum arabic, maltodextrine, sweet orange essential oil and sweet orange essential oil terpenless), sodium bicarbonate and sucralose.

What ACTEFF 600 looks like and contents of the pack

ACTEFF 600 effervescent tablets are round, flat, white to yellowish tablets with a score line. When an ACTEFF 600 effervescent tablet is dissolved in a glass of water, the appearance of the solution is clear with gas bubbles.

One polypropylene tube with a white polyethylene cap, containing a desiccant cage, and placed in an outer carton. Each tube contains 10 effervescent tablets.

Holder of Certificate of Registration

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