Approved Patient Information Leaflet for Medicines for Human Use:

AMUCO 200 Effervescent tablets

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AMUCO 200 effervescent tablets.

Read all of this leaflet carefully before you start to take AMUCO 200

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AMUCO 200** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AMUCO 200 CONTAINS

The active ingredient is N-Acetylcysteine.

The other ingredients are:

Citric acid anhydrous, orange flavour, sodium carbonate anhydrous sodium hydrogen carbonate, sorbitol, and the sweeteners saccharin sodium and sodium cyclamate.

2. WHAT AMUCO 200 IS USED FOR

AMUCO 200 is used as mucolytic (dissolves or breaks down mucus). It is used to treat chest conditions involving excessive or thickened mucus secretions for a maximum treatment period of 14 days.

3. BEFORE YOU TAKE AMUCO 200

Do not take AMUCO 200 if you:

If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of **AMUCO 200**.

Do not give **AMUCO 200 OTC** to children below the age of 2 years.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking **AMUCO 200.**

Take special care with AMUCO 200

AMUCO 200 should be used with caution if you:

- are asthmatic or if you have a history of stomach ulcers as **AMUCO 200** may cause nausea or vomiting which may result in bleeding in your stomach,
- if an allergic reaction to **AMUCO 200** occurs, stop taking the medicine and contact a doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or health care professional for advice before taking AMUCO 200.

The safety of **AMUCO 200** during pregnancy and breastfeeding has not been established. If you are taking **AMUCO 200** you should not breastfeed your baby.

Driving and using machinery

AMUCO 200 does not impair your ability to drive or operate machinery.

Using other medicines with AMUCO 200

Taking other medicines with AMUCO 200 OTC:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

If you are taking the following medicines or medicines containing the following, consult your doctor, pharmacist or other healthcare professional as these medicines may interact with **AMUCO 200:**

- A cough suppressant, as congestion of secretions may occur due to the impaired cough reflex.
- Tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics. These medicines must be administered separately of **AMUCO 200** and with an interval of at least two hours.

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

4. HOW TO USE AMUCO 200

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

Always take **AMUCO 200** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

THE USUAL DOSE IS:

As a mucolytic:

Children: 2 – 5 years: 100 mg (½ effervescent tablet) two to three times daily.

6 – 14 years: 200 mg (1 effervescent tablet) twice daily.

Adults: 200 mg (1 effervescent tablet) two to three times daily.

IF YOU HAVE THE IMPRESSION THAT THE EFFECT OF **AMUCO 200** IS TOO STRONG OR TOO WEAK, TALK TO YOUR DOCTOR OR PHARMACIST.

"Do not take medicines prescribed for you with others".

If you use more AMUCO 200 than you should

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your dose of AMUCO 200

It is important to use this medicine as prescribed by your doctor.

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to make up for the forgotten dose.

If you stop using AMUCO 200

If you want to stop using **AMUCO 200,** talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

AMUCO 200 can have side effects. Not all side effects reported for AMUCO 200 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMUCO 200 please consult your health care provider for advice.

If any of the following happens, stop taking AMUCO 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- anaphylaxis (skin rash, hives, itching, difficulty swallowing, puffiness or swelling of the eyelids or around the eyes, face, lips of tongue or fast heartbeat),
- bronchospasm, (narrowing of the air passages, difficulty breathing, or shortness of breath), rhinorrhoea,
- cardiac arrest,
- convulsions.

These are all very serious side effects. If you have them, you may have had a serious reaction to **AMUCO 200.** 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:

- nausea and vomiting,
- diarrhoea,
- stomatitis (inflammation of oral mucosa),
- syncope (fainting),
- headache,
- tinnitus (ringing in the ears),
- blurred vision,
- allergic dermatitis (skin rash, hives),
- chills, fever,
- acidosis,
- flushing, sweating,
- liver function disturbances,

- arthralgia (joint pain),
- allergic dermatitis and urticaria (skin rash or hives).

These are all serious side effects. You may need urgent medical attention.

Contact a doctor as soon as possible:

- Headache.
- Heartburn.
- Allergic dermatitis (skin rash).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF AMUCO 200

- Store in a cool, dry place, at or below 25 °C protected from light.
- The container must be tightly closed.
- Do not use after the date, which is stamped on the pack.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewage systems.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF AMUCO 200

White cylindrical polypropylene tube containing 8, 10, 12, 15, 20, 25, 30, 40 or 42 tablets sealed with a polyethylene cap containing silica gel in a unit carton.

Not all pack sizes may be marketed.

8. IDENTIFICATION OF AMUCO 200

White, round plane tablets, with an orange smell.

9. REGISTRATION NUMBER

43/10.2.2/0510

10. THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

www.austell.co.za

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on the registration certificate: 5 August 2011

Date of the most recently revised patient information leaflet as approved by council: 03 April 2022