

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

TUSSMUCO 200 mg effervescent tablets

N-acetylcysteine

Contains sugar: Glucose liquid 113 mg and mannitol 190 mg

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

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

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

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

1. What TUSSMUCO is and what it is used for

TUSSMUCO contains the active substance N-acetylcysteine.

It belongs to a group of medicines called mucolytics which works by thinning the mucus (phlegm) so that it can be coughed up more easily.

TUSSMUCO is used to treat:

- breathing difficulties caused by too much mucus in the lungs and airways or the mucus being too thick and sticky to cough up easily.

2. What you need to know before you take TUSSMUCO

Do not take TUSSMUCO:

- if you are hypersensitive (allergic) to N-acetylcysteine or any of the other ingredients of TUSSMUCO (listed in section 6).
- if you are pregnant.
- if you suffer from ulcers (sores) in your digestive tract.

Do not give TUSSMUCO to children under 2 years of age.

Warnings and precautions

Take special care with TUSSMUCO:

- if you have asthma.
- if you have been told that you have a sore that has developed on the lining of the oesophagus, stomach or small intestine known as a peptic ulcer.
- if you are unable to discharge matter from your throat or lungs as TUSSMUCO will liquefy phlegm and increase the volume. You need to be able to expectorate.
- do not use TUSSMUCO for more than 14 days without consulting with your doctor.

- there have been reports of hypersensitivity reactions with high fever, skin redness, joint pains and/or eye infections (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 consult a doctor immediately and stop using TUSSMUCO.
- if you are intolerant to histamine, TUSSMUCO may not be suitable for you because it affects how histamine is broken down in your body. The most common symptoms of histamine intolerance are headaches, runny nose and itching.

Other medicines and TUSSMUCO

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

Tell your doctor if you are taking any of the following:

- Antibiotics. Allow an interval of at least two hours between the antibiotics and TUSSMUCO effervescent tablets.
- Medicines used to suppress cough referred to as antitussives.
- Activated charcoal.
- Medicines such as nitroglycerin used to treat angina symptoms, such as chest pain.
- TUSSMUCO may affect certain tests such as urine tests.
- Do not mix TUSSMUCO with other medicines.

Pregnancy, breastfeeding and fertility

You should not take TUSSMUCO if you are pregnant or breastfeeding your baby.

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 this medicine.

Driving and using machines

TUSSMUCO is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that TUSSMUCO does not adversely affect your ability to do so safely (see section 4).

TUSSMUCO contains Glucose liquid 113 mg and mannitol 190 mg.

TUSSMUCO should not be taken if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take TUSSMUCO

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

The effervescent tablet must be dissolved in a glass of water before drinking it.

The usual dose of TUSSMUCO for adults and adolescents from 14 years of age is:

1 effervescent tablet 2 to 3 times daily.

For children from 6 to 14 years of age:

1 effervescent tablet twice daily.

For children from 2 to 5 years of age:

½ (half) an effervescent tablet 2 to 3 times daily.

Do not use the medicine for more than 14 consecutive days without consulting a doctor.

If you take more TUSSMUCO 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 overdose:

- If you have an uneasy feeling on your stomach with the need to vomit (nausea),
- vomiting,
- if you have liquid, or watery bowel movements when you go to the toilet (diarrhoea).
- Small children are at risk of excess production of bodily fluids such as mucus (increased discharge of phlegm).

If you forget to take TUSSMUCO

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

If you have missed a dose of TUSSMUCO, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

TUSSMUCO can have side effects.

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

If any of the following happens, stop taking TUSSMUCO 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 (anaphylactic shock, hypersensitivity, angioedema, dyspnoea, oedema of the face),
- rash or itching (urticaria),
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN).

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

- congestion of the lungs (bronchospasm),
- changes in the way your heart beats, for example, if you notice it beating faster (tachycardia).
- abnormal bleeding when you injure yourself (haemorrhage),

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:

- ringing in the ears (tinnitus),
- mouth wounds, swelling or sores in the mouth (stomatitis),
- pain that occurs between the chest and pelvic regions (abdominal pain),
- if you have liquid, or watery bowel movements when you go to the toilet (diarrhoea), vomiting, heartburn, indigestion, nausea,
- headache,
- fever,

- abnormally low blood pressure (hypotension),
- itchy skin which can result in redness, bumps, spots or blisters, dry, cracked, leathery or scaly skin (pruritus),
- a widely-spread rash accompanied by a fever (exanthema).

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: <https://www.sahpra.org.za/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TUSSMUCO.

5. How to store TUSSMUCO

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TUSSMUCO contains

The active substance is 200 mg N-acetylcysteine

The other ingredients are ascorbic acid, citric acid anhydrous, glucose liquid, lemon flavour, mannitol, sodium benzoate, sodium bicarbonate, sodium citrate, tartaric acid.

Lemon flavour consists of: Acacia gum 414, ascorbic acid 300, corn maltodextrin, flavouring preparation, natural flavouring substance.

What TUSSMUCO looks like and contents of the pack

TUSSMUCO is an effervescent tablet that is round, white to off white, mottled, flat plain on one side and a break line on the other side.

15 or 20 or 25 or 40 (2 x 20's) tablets are packed into a polypropylene tube with a white LDPE cap with a tamper seal and desiccant. The tube is packed into a cardboard carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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