



**Applicant:** Pharmacare Ltd  
**Product name:** TUSSMUCO 600  
**Dosage form and strength:** Each effervescent tablet contains 600 mg of acetylcysteine

**MODULE 1**  
1.3.2.1

### 1.3.2.1 Patient Information Leaflet

#### SCHEDULING STATUS

**S1**

#### TUSSMUCO 600 Effervescent Tablets

**Acetylcysteine 600 mg**

**Contains sugar: Glucose liquid 339 mg and mannitol 570 mg**

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

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

- Keep this leaflet. You may need to read it again.
- Do not share TUSSMUCO 600 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 600 and what it is used for
2. What you need to know before you take TUSSMUCO 600
3. How to take TUSSMUCO 600
4. Possible side effects

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5. How to store TUSSMUCO 600
6. Contents of the pack and other information

### 1. What TUSSMUCO 600 is and what it is used for

TUSSMUCO 600 contains the active substance called 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 TUSSMUCO 600

#### Do not take TUSSMUCO 600:

- If you are hypersensitive (allergic) to acetylcysteine or any of the other ingredients of TUSSMUCO 600 (listed in section 6).
- If you are pregnant or planning to become pregnant.
- If you have a history of stomach ulcers.

#### Warnings and precautions

Take special care with TUSSMUCO 600:

- If you develop a hypersensitivity reaction which may include but is not limited to severe blisters and bleeding of the lips, eyes, mouth, nose and genitals or fever, chills, aching muscles and generally feeling unwell (these are associated with skin conditions such as Stevens-Johnson syndrome or Lyell's syndrome) (see Possible side effects).
- If you have asthma.



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- As TUSSMUCO 600 liquifies thick phlegm, the amount of phlegm will increase. If you are unable to cough up this phlegm, consult your doctor to ensure effective steps are taken to remove this phlegm especially during the start of treatment with TUSSMUCO 600. This is of particular concern if you are an elderly or frail patient.
- If you suffer from histamine intolerance as TUSSMUCO 600 affects how your body breaks down histamine. General symptoms of histamine intolerance are usually headaches, runny nose and itching.
- If you have kidney or liver problems.

### **Children and adolescents**

- TUSSMUCO 600, should not be used in children less than 14 years of age (see section 3).

### **Other medicines and TUSSMUCO 600**

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:

- Any cough suppressant medicines.
- Any antibiotics especially antibiotics called 'tetracyclines'. TUSSMUCO 600 and these antibiotics should be taken 2 hours apart.
- Nitroglycerine or glyceryl trinitrate, which is used in heart failure, high blood pressure and to reduce pain associated with chest pains due to reduced blood



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flow also known as angina. Your doctor will need to monitor you, especially if you develop headaches.

- Blood pressure lowering medication especially a medicine classified as a 'angiotensin converting enzyme inhibitor (ACE inhibitor).
- Activated charcoal.

### **TUSSMUCO 600 with food and drink**

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

### **Pregnancy, breastfeeding and fertility**

You should not take TUSSMUCO 600 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 TUSSMUCO 600.

### **Driving and using machines**

It is not always possible to predict to what extent TUSSMUCO 600 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TUSSMUCO 600 affects you (see section 4).

### **TUSSMUCO 600 contains glucose:**

If you have been told that you have an intolerance to some sugars, you should not take TUSSMUCO 600.



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### 3. How to take TUSSMUCO 600

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

Always take TUSSMUCO 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.

Adults and adolescents from 14 years of age:

The usual dose of TUSSMUCO 600 is half (1/2) of an effervescent tablet taken twice daily or one (1) effervescent tablet taken once daily (equivalent to 600 mg acetylcysteine per day) fully dissolved in a glass of water taken after meals.

A clear solution is produced when TUSSMUCO 600 effervescent tablet is dissolved in a glass of water.

If a TUSSMUCO 600 effervescent tablet is not fully dissolved, it may cause choking and aspiration, particularly to elderly patients.

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

Children

Due to the high content of active substance (acetylcysteine 600 mg per tablet),

TUSSMUCO 600 should not be used in children less than 14 years of age.

**If you take more TUSSMUCO 600 than you should**



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

Overdoses may include stomach related irritations such as nausea, vomiting and diarrhoea.

Infants are at risk of producing an excessive amount of phlegm or mucous.

### **If you forget to take TUSSMUCO 600**

Do not take a double dose to make up for forgotten individual doses. TUSSMUCO 600 is indicated for once daily dosing (see section 3).

## **4. Possible side effects**

TUSSMUCO 600 can have side effects.

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

If any of the following happens, stop taking TUSSMUCO 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,
- rash or itching,
- fainting,



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- painful red areas, 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 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:

- Abnormal bleeding (haemorrhage) when you injure yourself.
- Yellowing of the skin and eyes, dark urine, and tiredness, which may be symptoms of liver problems (jaundice).
- Increased heartbeat (tachycardia).
- Shortness of breath (dyspnoea).
- Congestion of the lungs (bronchospasm),
- Sudden irregular movement of the body as a result of involuntary muscle contractions involuntary (convulsions).
- Temporary loss of consciousness (syncope).
- Increased blood pressure (hypertension)
- Painful, swollen joints as a result of a buildup of acid in the bloodstream (acidosis).

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

Tell your doctor if you notice any of the following:

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*Less frequent side effects:*

- Headache;
- blurred vision;
- ringing in the ears (tinnitus);
- lowered blood pressure;
- sudden reddening of the skin on the face, neck and upper chest due to increased blood flow (flushing);
- fever;
- painful, stiff joints (arthralgia);
- mouth wounds, swelling or sores in the mouth (stomatitis);
- nausea, diarrhoea, vomiting, stomach pains.

*Side effects with an unknown frequency:*

- Indigestion (dyspepsia).

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 via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088

By reporting side effects, you can help provide more information on the safety of TUSSMUCO 600.

## 5. How to store TUSSMUCO 600

- Store all medicines out of reach of children.
- Store below 25 ° C in a cool dry place.
- Do not use after the expiry date stated as 'Exp' on the label.
- Do not store in a bathroom.
- 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 600 contains

The active substance is acetylcysteine 600 mg.

The other ingredients are ascorbic acid, citric acid anhydrous, glucose liquid, lemon flavour, mannitol (E 421), sodium benzoate (E 211), sodium citrate, sodium hydrogen carbonate, tartaric acid.

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

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### **What TUSSMUCO 600 looks like and contents of the pack**

TUSSMUCO 600 effervescent tablets are round, white to off white, mottled, flat tablet, plain on one side and a break line on the other side.

10 tablets are packed into a polypropylene tube with a white low density polyethylene stopper with tamper evident seal and desiccant. The tube is packed into a cardboard carton.

### **Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

**Hotline:** 0800 122 912

### **This leaflet was last revised in**

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### **Registration number**

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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