1.3.1.1.1 Professional Information

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

TUSSMUCO 600 effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet of TUSSMUCO 600 contains 600 mg acetylcysteine.

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

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

TUSSMUCO 600 effervescent tablets are used as a mucolytic in acute respiratory conditions.

4.2. Posology and method of administration

Posology

Adults and adolescent from 14 years of age:

Take half (1/2) of an effervescent tablet dissolved twice daily or one (1) effervescent tablet dissolved once daily (equivalent to 600 mg acetylcysteine per day) (see Method of administration below).

Duration of use:

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

Paediatric population

Due to the high content of active substance, acetylcysteine 600 mg, as contained in TUSSMUCO 600, this medicine should not be used in children less than 14 years of age.

Method of administration

For oral administration:

The effervescent tablets are taken dissolved in a glass of water after meals.

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

4.3. Contraindications

TUSSMUCO 600 is contraindicated in:

- Patients with hypersensitivity to acetylcysteine, as contained in TUSSMUCO 600, or to any excipients in TUSSMUCO 600 (see section 6.1).
- Safety in pregnancy has not been established. TUSSMUCO 600 should not be used during pregnancy (see section 4.6).
- Active peptic ulceration.

4.4. Special warnings and precautions for use

Hypersensitivity

The occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome has been reported in temporal connection with the use of acetylcysteine, as contained in TUSSMUCO 600. If cutaneous and mucosal changes occur, consult your healthcare provider without delay and the use of acetylcysteine should be terminated (see section 4.8).

Respiratory, thoracic and mediastinal disorders

TUSSMUCO 600 should be used with caution in asthmatic patients. If bronchospasm occurs, the use of acetylcysteine, as contained in TUSSMUCO 600, must be stopped immediately and appropriate treatment initiated.

The use of acetylcysteine, as contained in TUSSMUCO 600, especially in early treatment can lead to liquefaction and thus to an increase in volume of bronchial secretions. If the patient is unable to sufficiently expectorate due to a reduced cough reflux e.g., elderly or frail patients, appropriate measures such as drainage and aspiration should be performed.

Gastrointestinal disorders

TUSSMUCO 600 should be used with caution in patients with a history of peptic ulcer disease, both because drug-induced nausea and vomiting may increase the risk of gastrointestinal haemorrhage in patients predisposed to the condition, and because of a theoretical risk that mucolytics may disrupt the gastric mucosal barrier (see section 4.3).

Choking hazard

The effervescent tablets should be dissolved fully before intake (see section 4.2). Not fully dissolved tablets present a risk of choking and aspiration, particularly to elderly patients.

Hepatic and renal impairment

Hepatic and renal impairment can reduce clearance and increase acetylcysteine, as contained in TUSSMUCO 600, plasma levels which may result in an increase in adverse medicine reactions due to medicine accumulation.

Intolerance

Caution is advised in patients with histamine intolerance. Treatment with acetylcysteine, as contained in TUSSMUCO 600, for longer periods should be avoided in such patients, as acetylcysteine affects histamine metabolism and can result in symptoms of intolerance (e.g., headache, runny nose, itching).

Excipients

TUSSMUCO 600 effervescent tablets contains glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.

4.5. Interaction with other medicines and other forms of interaction

Combined administration of TUSSMUCO 600 with antitussives may cause a dangerous secretory congestion due to the reduced cough reflex, so that an especially careful diagnosis is required for this combination treatment.

Tetracycline hydrochloride (with the exception of doxycycline) and other oral antibiotics must be administered separately from TUSSMUCO 600 and with an interval of at least 2 hours.

The concomitant administration of acetylcysteine, as contained in TUSSMUCO 600, can potentially result in an intensification of the vasodilatory and inhibition of platelet aggregation effects of glyceryl trinitrate (nitroglycerine). If concomitant treatment with glyceryl trinitrate and TUSSMUCO 600 is considered necessary, patients should be monitored for the possible development of hypotension, which can be serious, and advised of the possibility of headaches.

Angiotensin-converting enzyme (ACE) inhibitors: do not administer concurrently with ACE inhibitors, as acetylcysteine, as contained in TUSSMUCO 600, potentiates the anti-hypertensive effects.

Activated charcoal in high doses (as an antidote) can reduce the effectiveness of acetylcysteine.

Acetylcysteine, as contained in TUSSMUCO 600, can affect the colorimetric determination of salicylates.

In urine tests, acetylcysteine, as contained in TUSSMUCO 600, can affect the results of determinations of ketone bodies.

The dissolution of TUSSMUCO 600 together with other medicines is not recommended.

Acetylcysteine, as contained in TUSSMUCO 600, has a possible chelating effect and may reduce the bioavailability of certain heavy metal salts. As a precaution, TUSSMUCO 600 and heavy metal salts should be taken separately at different times of the day.

4.6. Fertility, pregnancy and lactation

Safety and efficacy of acetylcysteine, as contained in TUSSMUCO 600, in pregnancy and lactation have not been established (see section 4.3).

Pregnancy

There are no adequate clinical data from the use of acetylcysteine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. TUSSMUCO 600 should not be used during pregnancy.

Breastfeeding

No information is available regarding excretion of acetylcysteine or its metabolites into breast milk. A risk for the breast-fed child cannot be excluded. The use of acetylcysteine during breastfeeding is not recommended.

Fertility

Data concerning effects of acetylcysteine on human fertility are not available. In animal studies, no harmful effects on fertility were observed for therapy-relevant doses of acetylcysteine.

4.7. Effects on ability to drive and use machines

TUSSMUCO 600 has no known effect on the ability to drive and use machines.

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Immune system disorders		Hypersensitivity reactions	Anaphylactic shock, anaphylactic / anaphylactoid reactions, facial oedema

Nervous system disorders		Headache, convulsions, syncope	
Eye disorders		Blurred vision	
Ear and labyrinth disorders		Tinnitus	
Cardiac disorders		Tachycardia	
Vascular disorders		Haemorrhage, hypertension, hypotension	
Respiratory, thoracic and mediastinal disorders		Dyspnoea, bronchospasm - predominantly in patients with hyperactive reactive bronchial system in association with bronchial asthma	
Gastrointestinal disorders**		Nausea, vomiting, diarrhoea, abdominal pain, stomatitis	Dyspepsia
Hepatobiliary disorders		Disturbances of the liver function, acidosis	
Skin and subcutaneous tissue disorders		*Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria, rash, angioedema, itching, exanthema, pruritus, flushing	
Musculoskeletal and connective tissue disorders		Arthralgia	
General disorders and administrative site conditions		Fever	

b) Description of selected adverse reactions

*Severe skin reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in temporal association with the use of acetylcysteine.

If skin or mucous membrane abnormalities develop, the use of TUSSMUCO 600 must be discontinued immediately (see section 4.4).

A decreased blood platelet aggregation in the presence of acetylcysteine has been confirmed by different studies. The clinical relevance has not yet been clarified to date.
**In patients with peptic ulcer or a history thereof, acetylcysteine may have an undesirable effect on the gastric mucosa (see sections 4.3 and 4.4).

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Symptoms

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

Infants are at risk of hypersecretion.

Treatment

Treatment of overdose is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 10.3 Medicines acting on respiratory system, others.

Pharmacotherapeutic group: Mucolytics

ATC code: R05CB01

Mechanism of action

Acetylcysteine is a mucolytic medicine that reduces the viscosity of non-infected bronchial secretions probably by the splitting of disulphide bonds in mucoproteins. Acetylcysteine is a derivative of the amino acid cysteine. The efficacy of acetylcysteine is secretolytic and secretomotoric in the area of the respiratory tract. It splits off the interconnecting disulphide bonds between the mycopolysaccharide chains and that it has a depolymerising effect on DNA-chains (in purulent mucus).
This leads to a reduction in the viscosity of the mucus.

An alternative mechanism of acetylcysteine is meant to be based on the capacity of its reactive SH group to bind chemical radicals and to detoxify them in this way.

5.2. Pharmacokinetic properties

Absorption

Following oral administration, acetylcysteine is rapidly and almost completely absorbed and metabolised in the liver to cysteine, the pharmacologically active metabolite, as well as to diacetylcystine, cysteine and further mixed disulphides.

Distribution

Due to the high first-pass effect, the bioavailability of orally administered acetylcysteine is very low (approximately 10 %). Maximum plasma concentrations are achieved after 1 to 3 hours. The protein binding of acetylcysteine is approximately
50 %.

Acetylcysteine crosses the placenta and is detected in cord blood. No information is available regarding excretion into breast milk.

No knowledge is available concerning the behaviour of acetylcysteine at the blood-brain barrier in humans.

Biotransformation

Acetylcysteine and its metabolites occur in three different forms in the organism: partially in free form, partially bound to proteins via labile disulphide bonds and partially as incorporated amino acid.

Elimination

Acetylcysteine is excreted almost exclusively in the form of inactive metabolites (inorganic sulphates, diacetylcystine) via the kidneys. The plasma half-life of acetylcysteine is approximately 1 hour and is mainly determined by the rapid hepatic

biotransformation. Impaired hepatic function therefore leads to prolonged plasma half-lives of up to 8 hours.

Pharmacokinetic studies with intravenous administration of acetylcysteine revealed a distribution volume of 0,47 L/kg (in total) or 0,59 L/kg (reduced); the plasma clearance was determined to be 0,11 L/h/kg (in total) and 0,84 L/h/kg (reduced), respectively. The elimination half-life after intravenous administration is 30 to 40 minutes while excretion follows three-phase kinetics (alpha, beta, and terminal gamma phase).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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.

6.2. Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicines

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25 ° C in a cool dry place.

6.5. Nature and contents of container

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.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

Tel: 0800 122 912

8. REGISTRATION NUMBER

59/10.3/0104

9. DATE OF FIRST AUTHORISATION

25 November 2025

10. DATE OF REVISION OF TEXT

25 November 2025

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.