SCHEDULING STATUS:

S1

1. NAME OF THE MEDICINE

CORENZA MUCO 200

CORENZA MUCO 600

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

CORENZA MUCO 200:

Each effervescent tablet contains:	
Acetylcysteine	200 mg

CORENZA MUCO 600:

Each effervescent tablet contains:	
Acetylcysteine	600 mg

Contains sweetener: sodium saccharin 20 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Effervescent Tablet.

200 mg: White to off white round, flat, effervescent tablets

600 mg: white round flat tablets

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

CORENZA MUCO is used as a mucolytic in acute respiratory conditions.

4.2 Posology and method of administration

Posology:

CORENZA MUCO 200:

Children from 2-5 years of age: ½ (half) an effervescent tablet 2 to 3 times a day. (equivalent to 200 to 300 mg acetylcysteine/day).

Children from 6-14 years of age: 1 effervescent tablet twice daily (equivalent to 400 mg acetylcysteine/day).

Adults & adolescents from 14 years of age: 1 effervescent tablet 2 to 3 times daily (equivalent to 400 to 600 mg acetylcysteine/day).

CORENZA MUCO 600:

Adults & adolescents from 14 years of age: 1 effervescent tablet daily or ½ effervescent tablet twice daily (equivalent to 600 mg acetylcysteine per day).

Do not exceed the recommended dosage.

Method of administration:

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

Duration of use: Do not use continuously for more than 14 days without medical advice.

4.3 Contraindications

- Known hypersensitivity to the acetylcysteine or to any of the excipients listed under Section 6.1.
- Should not be used in pregnancy & breastfeeding (see Section 4.6)
- Active peptic ulceration.
- Children below 2 years of age

4.4 Special warnings and precautions for use

- Patients with bronchial asthma should be closely monitored during therapy, if bronchospasm occurs, treatment should be discontinued immediately and appropriate treatment initiated.
- Mucolytics can induce bronchial obstruction in children under 2 years of age. In fact, the drainage capacity of bronchial mucus is limited in this age group, due to the physiological characteristics of the respiratory tract. They should therefore not be used in children less than 2 years of age (see section 4.3).
- The use in patients affected by peptic ulcer or with a history of peptic ulcer requires special attention, especially in case of concurring intake of other medicines with known harmful effects on the gastrointestinal tract.
- Administration of N-acetylcysteine, especially early on in the treatment, is known for its thinning effect on bronchial secretions, and for simultaneously increasing their volume. If the patient is unable to expectorate effectively, in order to avoid retention of secretions, it is necessary to employ postural drainage and broncho aspiration.
- CORENZA MUCO can affect histamine metabolism. Therefore, caution should be used when administering CORENZA MUCO to patients with histamine intolerance, as doing so may lead to symptoms of hypersensitivity.
- The occurrence of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome has very rarely been reported in temporal connection with the use of acetylcysteine. If cutaneous and mucosal changes occur, the use of CORENZA MUCO must be terminated without delay (see section 4.8).

4.5 Interaction with other medicines and other forms of interaction

Interactions with other medicines

- It is advisable not to mix other medicines with the CORENZA MUCO mucolytic solution.
- Combined administration of CORENZA MUCO 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 CORENZA MUCO and with an interval of at least 2 hours.
- The concomitant administration of acetylcysteine 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 CORENZA MUCO is considered necessary, patients should be monitored for the possible development of hypotension, which can be serious, and advised of the possibility of headaches.
- *Activated charcoal* in high doses (as an antidote) can reduce the effectiveness of CORENZA MUCO.

Interactions with laboratory tests

- CORENZA MUCO can affect the colorimetric determination of salicylates.
- In urine tests, CORENZA MUCO can affect the results of determinations of ketone bodies.

4.6 Fertility, pregnancy and lactation

Safety and efficacy of acetylcysteine in pregnancy and lactation have not been established (see section 4.3). No fertility data available.

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. CORENZA MUCO 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

CORENZA MUCO does not affect the ability to drive and use machines.

4.8 Undesirable effects

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system.

System Organ Class	***Frequency***	***Undesirable effect***
Immune system disorders	Less Frequent	Hypersensitivity, Anaphylactic shock, anaphylactic/ anaphylactoid reaction
Nervous system disorders	Less Frequent	Headache
Eye disorders	Less Frequent	Blurred vision
Ear and labyrinth disorders	Less Frequent	Tinnitus
Cardiac disorders	Less Frequent	Tachycardia
Vascular disorders	Less frequent	Haemorrhage
Respiratory, thoracic and mediastinal disorders	Less frequent	Bronchial spasms, dyspnoea
	Frequency unknown	Bronchial obstruction
Gastrointestinal disorders	Less Frequent	Vomiting, diarrhoea, stomatitis, abdominal pain, nausea, dyspepsia.
Hepato-biliary disorders	Less Frequent	Disturbances of the liver function, acidosis.

Skin and subcutaneous tissue disorders	Less Frequent	*Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria, rash, angioedema, itching, exanthema, pruritus, flushing.
Musculoskeletal and connective tissue disorders	Less Frequent	Arthralgia
General disorders and administration site conditions	Less Frequent	Pyrexia, hypotension
	Frequency unknown	Oedema of the face

*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 CORENZA MUCO must be discontinued immediately.
- A decreased blood platelet aggregation in the presence of CORENZA MUCO has been confirmed by different studies. The clinical relevance has not yet been clarified to date.

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.

Adverse Drug Reactions may also be reported to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

4.9 Overdose

Overdose can cause gastrointestinal symptoms such as nausea, vomiting and diarrhoea. Treatment of overdose is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological classification: A 10.3 Medicines acting on the respiratory system - other.

Pharmacotherapeutic group: Cough and cold preparations; Mucolytics

ATC Code: R05CB01.

5.1 Pharmacodynamics properties

Acetylcysteine, is a mucolytic agent, which is a derivative of the amino acid cysteine. It reduces the viscosity of non-infected bronchial secretions probably by the splitting of 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. The efficacy of acetylcysteine is thus secretolytic and secretomotoric in the area of the respiratory tract.

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: 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 (approx. 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. 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.

Elimination: 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). Acetylcysteine is excreted almost exclusively in the form of inactive metabolites (inorganic sulphates, diacetylcystine) via the kidneys.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Citric acid
- Leucine
- Maltodextrin [E1400]
- Orange flavour
- Purified water
- Saccharin sodium [E954]
- Sodium hydrogen carbonate [E500].

6.2 Incompatibilities

It is advisable not to mix other drugs with the CORENZA MUCO solution.

6.3 Shelf life

Shelf Life: 3 years.

After opening: 90 days.

6.4 Special precautions for storage

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

Protect from light.

Keep the tubes tightly closed in order to protect from moisture.

Keep the tube in the carton until required for use.

6.5 Nature and contents of container

Polypropylene tube closed with a polyethylene stoppers equipped with silica gel as drying agent. The tube is inserted into cardboard boxes with the leaflet.

CORENZA MUCO 200 & 600 Pack sizes: 10’s, 20’s.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road, Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK /232625.

8. REGISTRATION NUMBERS:

CORENZA MUCO 200 : 57/10.3/0863

CORENZA MUCO 600 : 57/10.3/0864.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 September 2025.

10. DATE OF REVISION OF THE TEXT

To be allocated.