SUMMARY OF PRODUCT CHARACTERISTICS

MUCOLEX 5 (CARBOCISTEINE SYRUP 5 % W/V)

1. Qualitative and quantitative composition

Each 10 ml contains:
Carbocisteine B . P 500 mg
Flavoured syrupy base q.
s Colour: Caramel
For the full list of excipients, see section 6.1.

2. Pharmaceutical form

Oral Syrup

A Brown coloured syrup

3. Posology

3.1 Therapeutic Indications

Treatment of bronchial secretion disorders, especially during acute disorders of the bronchial tree: acute bronchitis and acute episodes of chronic bronchopneumopathy.

3.2 Posology and Method of Administration

Posology
Adults
The usual dose is 15ml three times daily initially, reducing to reducing to 10 ml 3 times a day when a satisfactory response has been obtained.
Children aged 6 to 12 years:
5 ml two to three times daily.

3.3 Contraindications

Hypersensitivity to carbocisteine, the active substance or to any of the excipients listed in section 6.1.
Active peptic ulcer disease.

3.4 Special warnings and precautions for use

Special warnings

In case of productive cough with purulent sputum, in case of fever or chronic disease of the bronchial tree or lungs, the clinical situation should be reassessed. Productive cough, which is a basic part of the bronchopulmonary defence mechanism, should not be suppressed. It is irrational to combine bronchial fluidifying agents with antitussives and/or medications for drying respiratory secretions (atropine).
Mucolytics can induce bronchial congestion in infants. The capacity for draining bronchial mucus is limited in infants due to the physiological characteristics of their respiratory tree. They should not be used in infants. Treatment should be reassessed in case of persistence or worsening of the symptoms or disease.

Special precautions for use

Caution is recommended in patients with gastroduodenal ulcers. This medicinal product contains sucrose. Its use is not recommended in patients with fructose intolerance, or glucose-

galactose malabsorption syndrome or sucrase/isomaltase insufficiency. This medicinal product contains 2 g of sucrose per 5 ml dose which should be taken into account in the daily ration in patients on a low-sugar diet or with diabetes. This medicinal product contains sodium. This should be taken into account in patients on a controlled sodium diet.

3.5 Interaction with other medicinal products and other forms of interaction

An expectorant or mucolytic medicinal product should not be combined with an antitussive medicinal product or a medicinal product indicated for use to dry secretions (such as anticholinergics). No interaction studies have been performed.

3.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of carbocisteine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Therefore, the use during pregnancy is not recommended unless under the guidance of a medical practitioner.

Lactation

There is insufficient information on the excretion of carbocisteine and metabolites in human milk. A risk to newborns/infants cannot be excluded. Therefore, the use is not recommended during breast-feeding.

3.7 Effects on ability to drive and use machines

Carbocisteine has no or negligible influence on the ability to drive and use machines.

3.8 Undesirable effects

Adverse reactions listed by System Organ Class. Frequencies are defined using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to ≤1/100); rare (≥1/10,000 to ≤1/1,000); very rare (≤1/10,000); not known (cannot be estimated from the available data).

Cardiac disorders: Rare: Palpitations.

Endocrine disorders: Not known: Hypothyroidism.*

Gastrointestinal disorders: Uncommon: Nausea, vomiting and diarrhoea. Very rare: Gastrointestinal bleeding. Not known: Gastric discomfort.

Immune system disorders: Rare: Urticaria and bronchospasm.** Very rare: Rash.

Musculoskeletal and connective tissue disorders: Rare: Muscle pain.

Nervous system disorders: Rare: Headache, dizziness, urinary incontinence, palpitations.

Respiratory, thoracic and mediastinal disorders: Rare: Shortness of breath. Not known: Bronchorrhoea.

Skin and subcutaneous tissue disorders: Not known: Stevens-Johnson syndrome, erythema multiforme.

* Special attention in patients with compromised thyroid function due to the risk of transient hypothyroidism occurrence.** Special attention in asthmatic patients due to the risk of bronchoconstriction occurrence (contraction of a muscle of the bronchial wall that leads to a reduction in airflow). In these cases, treatment discontinuation is recommended.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Agents.

3.9 Overdose

Gastrointestinal disturbance is the most likely symptom of overdosage. The treatment should be symptomatic and supportive.

4. Pharmacological properties

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: MUCOLYTICS, ATC code: R05CB03 (R: respiratory system)

Mechanism of action

Carbocisteine is a mucolytic-type mucomodifier. It exerts its action on the gel phase of the mucus, probably by breaking the disulphide bonds of the glycoproteins and thus aids expectoration. Moreover, carbocisteine has effects on bronchial secretion by normalization of mucus hyperviscosity.

4.2 Pharmacokinetic properties

Absorption

Carbocisteine is rapidly absorbed following oral administration; the plasma peak is reached in two hours.

Distribution and biotransformation

The bioavailability is low, less than 10% of the dose administered which is probably due to intraluminal metabolism and a marked liver first-pass effect.

Elimination

The elimination half-life is approximately 2 hours. Both it and its metabolites are mainly eliminated via the kidneys.

4.3 Preclinical safety data

No information further to that contained in other sections of the SPC is included.

5. Pharmaceutical particulars

5.1 List of excipients

SR. NO	INGREDIENTS
1.	PROPYLENE GLYCOL
2.	SODIUM HYDROXIDE PELLETS
3.	GLYCERIN
4.	PULVIS SUCROSE
5.	SWEET ORANGE FLAVOUR
6.	CARAMEL COLOUR
7.	PURIFIED WATER

5.2 Incompatibilities

None known

5.3 Shelf life

36 Months

5.4 Special precautions for storage

Store below 30°C. Do not refrigerate or freeze

5.5 Nature and contents of container
100 ml HDPE Bottle.

5.6 Special precautions for disposal and other handling
None.

7 Marketing Authorization Holder and Manufacturing Site Address

Marketing Authorization Holder:
Krishna Chemists Limited
PO Box:3328-00506,
Nairobi-Kenya

Manufactured in India by:
RELAX BIOTECH PVT LTD.
862/1, GIDC Makarpura, Vadodara-390010., Gujarat, India.

8 Marketing Authorization Number
CTD11427

9. Date of first Registration/ Renewal of the Registration

23/07/2026

10. Date of Revision of the Text

23/07/2026