

PROFESSIONAL INFORMATION FOR MUCOSOLV CAPSULES

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

MUCOSOLV CAPSULES 375 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains: carbocisteine 375 mg

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

Orange/white hard gelatin capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MUCOSOLV CAPSULES is indicated as adjunctive therapy in respiratory tract disorders characterised by excessive viscous mucous in the absence of infection.

4.2 Posology and method of administration

Posology

Adults: Take two (2) capsules three (3) times daily, reducing to one (1) capsule four (4) times daily when a satisfactory response has been obtained.

Method of administration

MUCOSOLV CAPSULES are for oral use only.

4.3 Contraindications

Hypersensitivity to any of the ingredients, including excipients listed in section 6.1.

Use in patients with active peptic ulceration.

4.4 Special warnings and precautions for use

MUCOSOLV CAPSULES must be used with caution in patients with a history of peptic ulcer or duodenal disease because of the risk that mucolytics may disrupt the gastric mucosal barrier.

4.5 Interaction with other medicines and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

MUCOSOLV CAPSULES have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders

Frequency unknown: Anaphylactic reactions, allergic skin eruption and fixed drug eruption

Gastrointestinal disorders

Frequent: Nausea, diarrhoea, gastric discomfort

Less frequent: Gastro-intestinal bleeding

Frequency unknown: vomiting

Skin and subcutaneous tissue disorders

Less frequent: Skin rashes

Frequency unknown: allergic skin eruptions. Isolated cases of dermatitis bullous such as Stevens-Johnson syndrome and erythema multiforme have also been reported.

General disorders and administrative site conditions

Less frequent: Headache

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 asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> and to Cipla Medpro (Pty) Ltd at drugsafety@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Gastrointestinal disturbance is the most likely symptom of MUCOSOLV CAPSULES overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification:

A 10.1 Antitussives and expectorants

ATC code: R05CB03

Carbocisteine reduces the viscosity of non-infected secretions from mucous cells in the respiratory tract.

Carbocisteine is used for its mucolytic activity in respiratory disorders associated with productive cough.

5.2 Pharmacokinetic properties

Carbocisteine is rapidly and well absorbed from the gastrointestinal tract and peak plasma concentrations occur about two (2) hours after an oral dose. It appears to penetrate into lung tissue and respiratory mucus. Carbocisteine is excreted in the urine as unchanged substance and metabolites. Acetylation, decarboxylation, and sulfoxidation have been identified as the major metabolic pathways. Sulfoxidation may be governed by genetic polymorphism.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silicon dioxide

Magnesium stearate

Maize starch

Microcrystalline cellulose

Povidone K-25

Purified talc

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

MUCOSOLV CAPSULES are orange/white hard gelatine capsules.

MUCOSOLV CAPSULES are packed in blister strips of 10 capsules packed in cartons of 30 or 100 capsules per carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Cipla Medpro (Pty) Ltd.

Building 9, Parc du Cap

Mispel Street

Bellville

7530, RSA

Customer care: 080 222 6662

8. REGISTRATION NUMBER

W/10.1/ 57

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The date on the registration certificate of the medicine: 19 December 1988

10. DATE OF REVISION OF THE TEXT

11/11/2022