Professional information for LESSMUSEC

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

LESSMUSEC, 375 mg capsules, hard.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 375 mg carbocisteine.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules, hard.

Red cap and orange body, size 0 capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adjunctive therapy in respiratory tract disorders characterised by excessive viscous mucus in the absence of infection.

4.2 Posology and method of administration

Posology

Adults: Two capsules three times daily, reducing to one capsule four times daily after satisfactory response has been obtained.

Paediatric population

No data available.

Method of administration

LESSMUSEC is for oral use only.

4.3 Contraindications

- Hypersensitivity to carbocisteine or any of the excipients of LESSMUSEC listed in section 6.1.
- Use in patients with an active peptic ulcer.

4.4 Special warnings and precautions for use

LESSMUSEC should be used with caution in elderly patients, those with a history of gastroduodenal ulcers, or those taking concomitant medicines known to cause gastrointestinal bleeding due to the risk of disruption of the gastric mucosal barrier. If gastrointestinal bleeding occurs, LESSMUSEC therapy should be discontinued.

Transient hypothyroidism may develop in patients with compromised thyroid function.

Excipient warnings

LESSMUSEC contains Sunset Yellow FCF (E110), ponceau 4R (E124) and carmoisine (E122) which may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction

Incompatible with pholcodine linctus.

4.6 Fertility, pregnancy and lactation

Safety and efficacy during pregnancy and lactation have not been established.

Pregnancy

There are no available data on carbocisteine use in pregnant women. The use of carbocisteine in pregnant women is not recommended.

Breastfeeding

There are no available data on the presence of carbocisteine in human milk, milk production, or the effects on the breastfed infant. The use of carbocisteine in breastfeeding women is not recommended.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

LESSMUSEC is not likely to affect the ability to drive a vehicle or operate machinery. However, patients must take care until they know how they will react to LESSMUSEC.

4.8 Undesirable effects

Immune system disorders

Frequency unknown: Anaphylactic reactions, allergic skin eruption and fixed medicine eruption.

Nervous system disorders

Frequency unknown: Dizziness, headache.

Cardiac disorders

Frequency unknown: Palpitations.

Gastrointestinal disorders

Frequency unknown: Nausea, heartburn, diarrhoea, epigastric discomfort, gastrointestinal bleeding, vomiting.

Skin and subcutaneous tissue disorders

Frequency unknown: Skin rash, bullous dermatitis, Stevens-Johnson syndrome, erythema multiforme.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of LESSMUSEC is important. It allows continued monitoring of the benefit/risk balance of LESSMUSEC. 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

4.9 Overdose

See sections 4.4 and 4.8.

Gastrointestinal disturbance is the most likely symptom of LESSMUSEC overdosage.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: A 10.1 Antitussives and expectorants.

Pharmacotherapeutic group: Respiratory system, mucolytics.

ATC code: R05CB03.

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

Carbocisteine is absorbed from the gastrointestinal tract.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content

Magnesium stearate

Maize starch

Purified talc.

Capsule shell

Colourants (carmoisine (E122), erythrosine (E127), ponceau 4R (E124), Sunset Yellow FCF (E110), titanium dioxide)

Gelatine.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from light and moisture.

Keep container tightly closed until required for use.

6.5 Nature and contents of container

White HDPE cylindrical securitainer with a white HDPE snap-on cap. The container also includes a desiccant.

OR

2,5 litre white polypropylene bucket lined with a plastic bag (polyethylene) with a white polypropylene push-on lid. The bucket also includes a desiccant.

Pack sizes: 20, 30 or 1 000 capsules.

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

Brunel Laboratoria (Pty) Ltd

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Centurion

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8. REGISTRATION NUMBER

T/10.2.2/227

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

April 1998

10. DATE OF REVISION OF THE TEXT

30 March 2023