

PACKAGE INSERT FOR LESSMUSEC CAPSULES

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

LESSMUSEC CAPSULES

COMPOSITION:

Active ingredient:

Each capsule contains 375 mg carbocisteine.

Inactive ingredients:

Gelatine, magnesium stearate, maize starch, purified talc and colourants (brilliant blue FCF, erythrosine, sunset yellow FCF and titanium dioxide).

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

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

Pharmacokinetic properties:

Carbocisteine is absorbed from the gastrointestinal tract.

INDICATIONS:

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

CONTRAINDICATIONS:

Hypersensitivity to carbocisteine or any of the inactive ingredients of **LESSMUSEC CAPSULES** (see **COMPOSITION**).

An active peptic ulcer.

WARNINGS AND SPECIAL PRECAUTIONS:

LESSMUSEC CAPSULES should be used with caution in patients with a history of peptic ulcer disease, due to the risk of disruption of the gastric mucosal barrier.

Transient hypothyroidism may develop in patients with compromised thyroid function.

Effects on ability to drive and use machines:

LESSMUSEC CAPSULES 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 CAPSULES**.

INTERACTIONS:

Incompatible with pholcodine linctus.

PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

LESSMUSEC CAPSULES is for oral use only.

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

SIDE EFFECTS:**Immune system disorders:**

Frequency unknown: Anaphylactic reactions, fixed drug eruption.

Nervous system disorders:

Frequency unknown: Dizziness, headache.

Cardiac disorders:

Frequency unknown: Palpitations.

Gastrointestinal disorders:

Frequency unknown: Nausea, heartburn, diarrhoea, gastric discomfort, gastrointestinal bleeding.

Skin and subcutaneous tissue disorders:

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

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

See **WARNINGS AND SPECIAL PRECAUTIONS** and **SIDE EFFECTS**.

Gastrointestinal disturbance is the most likely symptom of **LESSMUSEC CAPSULES** overdosage. Treatment is symptomatic and supportive.

IDENTIFICATION:

Scarlet cap and orange body, size 0 capsule.

PRESENTATION:

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

OR

White 2 litre HDPE container with a white HDPE clip-on lid. The container also includes a desiccant. Pack sizes: 20, 30 or 1000 capsules.

STORAGE INSTRUCTIONS:

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

Keep container tightly closed until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

T/10.2.2./227

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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