1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAMES AND DOSAGE FORMS

MUCOSPECT PED (syrup)

MUCOSPECT SYRUP

MUCOSPECT CAPSULES

COMPOSITION

Each 5 ml of MUCOSPECT PED contains 125 mg carbocysteine.

Excipients:

Colour carmosine red (C.I. 14720), disodium edetate, flavour cherry essence no. 1, flavour raspberry essence no. 1, flavour vanilla essence no. 1, methyl hydroxybenzoate, purified water, sodium hydroxide, sucrose

Preservative: Methyl hydroxybenzoate 0,17 % *m/v.*

Contains sugar: Sucrose 2,00 g

Alcohol and tartrazine free

Each 5 ml of MUCOSPECT SYRUP contains 250 mg carbocysteine.

Excipients:

Flavour cherry essence no. 1, glycerol, methyl hydroxybenzoate, ponceau 4R (C.I. 16255), purified water, sodium hydroxide, sucrose

Preservative: Methyl hydroxybenzoate 0,17 % *m/v*

Contains sugar: Sucrose 1,90 g

Alcohol and tartrazine free

Each capsule MUCOSPECT CAPSULES contains 375 mg carbocysteine.

Excipients:

Black iron oxide (C.I. 77499), erythrosine (C.I. 45430), gelatin, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch, quinoline yellow (C.I. 47005), colloidal silicon dioxide, starch maize, talc purified, titanium dioxide (C.I. 77891)

Sugar free

CATEGORY AND CLASS

A 10.1 Expectorants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

INDICATIONS

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

CONTRAINDICATIONS

- Active peptic ulcer.
- The safety in pregnancy has not been established.
- Incompatible with pholcodeine linctus.

WARNINGS AND SPECIAL PRECAUTIONS

Caution must be exercised in patients with a history of gastric or duodenal ulcer.

Excipients

Sucrose warning:

MUCOSPECT PED and MUCOSPECT SYRUP contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take MUCOSPECT PED and MUCOSPECT SYRUP.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

The safety in pregnancy has not been established (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

MUCOSPECT PED

Children (2 to 5 years): A half to one medicine measure (2,5 ml to 5 ml) three times daily.

Children (5 to 12 years): 2 medicine measures (10 ml) three times daily.

MUCOSPECT SYRUP

Adults: 2 to 3 medicine measures (10 to 15 ml) three times daily.

Children (5 to 12 years): 1 medicine measure (5 ml) three times daily.

MUCOSPECT CAPSULES

Adults: 2 capsules three times daily, reducing to 1 capsule four times daily when a satisfactory response has been obtained.

SIDE EFFECTS

Nausea, diarrhoea, headache, dizziness, palpitations and heartburn may occur. Gastrointestinal bleeding and skin rash may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

See SIDE EFFECTS.

Treatment is symptomatic and supportive.

IDENTIFICATION

MUCOSPECT PED

A clear, red syrupy liquid with a raspberry odour.

MUCOSPECT SYRUP

A clear, red syrupy liquid with a cherry odour.

MUCOSPECT CAPSULES

A no. 0 hard gelatin capsule with an opaque orange cap and opaque white body, with “mucospect” imprinted in black ink on both cap and body, containing a white to off-white powder.

PRESENTATION

MUCOSPECT PED

100 ml are packed into a round, clear glass bottle and sealed with a white polypropylene cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

MUCOSPECT SYRUP

200 ml are packed into a round, amber glass bottle and sealed with a white, polypropylene cap with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

2,5 ℓ are packed into a green, high density polyethylene tamper evident plastic can sealed with a white, polypropylene ratchet cap together with a leaflet.

MUCOSPECT CAPSULES

30 capsules are packed in clear polyvinylchloride blister strips sealed with an aluminium foil backing and are packed into an outer cardboard carton together with a leaflet.

100 capsules are packed in a white polypropylene container and sealed with a white low-density polyethylene cap together with a white foam insert. The container is packed into an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

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

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS

MUCOSPECT PED W/10.1/216

MUCOSPECT SYRUP L/10.1/318

MUCOSPECT CAPSULES P/10.1/186

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration:

MUCOSPECT PED: 16 June 1989

MUCOSPECT SYRUP: 28 August 1979

MUCOSPECT CAPSULES: 07 September 1982

Date of the most recent amendment to the professional information as approved by the Authority:

16 June 1989

Namibia: NS1

MUCOSPECT PED: 90/10.1/001622

MUCOSPECT SYRUP: 90/10.1/001623

MUCOSPECT CAPSULES: 90/10.1/001621

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