SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

BORSTOL LINCTUS-ORANGE FLAVOUR (emulsion)

COMPOSITION

Each 10 ml of BORSTOL LINCTUS-ORANGE FLAVOUR emulsion contains 200 mg guaiphenesin.

Excipients:

Arachis oil, butylated hydroxyanisole, colour spectracol sunset yellow (C.I. 15985), ethanol, flavour orange tetratome, menthol levo, purified water, sodium benzoate, sodium cyclamate, sodium saccharin, sucrose

Preservative: Sodium benzoate 0,10 % *m/v*

Contains alcohol: 10,56 % *v/v*

Contains sugar: Sucrose 676 mg

Contains sweeteners: Sodium cyclamate 20 mg, sodium saccharin 5 mg

CATEGORY AND CLASS

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Guaiphenesin has an expectorant action.

INDICATIONS

The alleviation of cough associated with viscid or tenacious phlegm.

CONTRAINDICATIONS

- Sensitivity to any of the ingredients.
- Porphyria.
- Safety in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

BORSTOL LINCTUS-ORANGE FLAVOUR should not be taken for persistent cough such as occurs with smoking, asthma, emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a doctor.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur or is accompanied by high fever, rash or persistent headache, consult a doctor.

BORSTOL LINCTUS-ORANGE FLAVOUR should not be given to children under 2 years unless recommended by a doctor.

BORSTOL LINCTUS-ORANGE FLAVOUR contains sodium benzoate which is a mild irritant to the skin, eyes and mucous membranes.

Excipients

Sucrose warning:

BORSTOL LINCTUS-ORANGE FLAVOUR 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 BORSTOL LINCTUS-ORANGE FLAVOUR.

INTERACTIONS

Guaiphenesin interferes with urine tests for 5-hydroxyindolacetic acid (5-HIAA) and vanillylmandelic acid.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

Shake the bottle well.

Adults: 10 ml every 4 hours.

Do not exceed 6 doses of 20 ml in 24 hours.

SIDE EFFECTS

Diarrhoea, dizziness, headache, skin rash, stomach pains, urticaria. Gastrointestinal discomfort has occasionally been reported.

Very large doses cause nausea and vomiting.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

In the event of an overdose, consult a doctor or take the patient to the nearest hospital immediately. Symptoms of overdosage include nausea and vomiting.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

Orange emulsion which separates on standing.

PRESENTATION

50, 100 or 200 ml are packed in an amber or clear glass bottle with a black aluminium roll on cap, internally lacquered and lined with an expanded polyethylene liner. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in a cool place, protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Y/10.1/52

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

Date of registration: 17 May 1991

Date of the most recent amendment to the professional information as approved by the Authority: 17 May 1991

ZA_BORSOEML_9105_01