1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

LENNON COUGH MIXTURE ORANGE (syrup)

COMPOSITION

Each 5 ml of LENNON COUGH MIXTURE ORANGE syrup contains 100 mg guaiphenesin.

Excipients:

Colour spectracol sunset yellow (C.I. 15985) or Dye Lennon yellow (C.I. 15985), flavour sweet orange essence, glycerol, hydroxyethylcellulose, povidone, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium saccharin, sorbitol solution

Preservative: Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol 1,3 g

Contains sweetener: Sodium saccharin 25 mg

Alcohol free

CATEGORY AND CLASS

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Guaiphenesin is an expectorant that increases the volume and reduces the viscosity of tenacious sputum.

Pharmacokinetic properties

Guaiphenesin is absorbed from the gastrointestinal tract. It is metabolised and excreted in the urine.

INDICATIONS

LENNON COUGH MIXTURE ORANGE is indicated for the alleviation of cough associated with viscid/tenacious phlegm.

CONTRAINDICATIONS

LENNON COUGH MIXTURE ORANGE is contraindicated in:

- Hypersensitivity to any of the ingredients.
- Pregnancy and lactation.
- Not recommended for children under 2 years of age.
- Porphyria.

WARNINGS AND SPECIAL PRECAUTIONS

- Do not take for persistent cough such as that which occurs with smoking, asthma, emphysema or where cough is accompanied by excessive by 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 medical practitioner.

Excipients

Contains sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take LENNON COUGH MIXTURE ORANGE.

INTERACTIONS

Interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid.

HUMAN REPRODUCTION

The safety of LENNON COUGH MIXTURE ORANGE in pregnancy and lactation has not been established (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Adults and children 12 years and over:

200 mg to 400 mg (10 ml to 20 ml) orally, every 4 hours. Do not exceed 2 400 mg (120 ml) in 24 hours.

6 to 12 years:

100 mg to 200 mg (5 ml to 10 ml), orally every 4 hours. Do not exceed 1 200 mg (60 ml) in 24 hours.

2 to 6 years:

50 mg to 100 mg (2,5 ml to 5 ml) orally every 4 hours. Do not exceed 600 mg (30 ml) in 24 hours, or as directed by a medical practitioner.

SIDE EFFECTS

Nervous system disorders

Less frequent: Headache, dizziness

Frequency unknown: Drowsiness

Gastrointestinal disorders

Less frequent: Diarrhoea, nausea, vomiting, stomach pains

Frequency unknown: Discomfort

Skin and subcutaneous tissue disorders

Less frequent: Rash, urticaria

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Treatment is symptomatic and supportive.

IDENTIFICATION

A clear, orange, slightly viscous liquid.

PRESENTATION

50 ml or 100 ml is packed in an amber glass bottle with a white, cylindrical, polypropylene tamper evident duet screw cap, with a liner. Each bottle will be placed in a unit carton.

50 ml or 100 ml is packed in a round, opaque, white high-density polyethylene bottle with a white low-density polyethylene snap cap type closure. Each bottle will be placed in a unit carton.

50 ml or 100 ml is packed in a flint glass bottle with a white, cylindrical, polypropylene tamper

evident duet screw cap, with a liner. Each bottle will be placed in a unit carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C in tightly closed containers.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A38/10.1/0362

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: 07 July 2006

Date of the most recent amendment to the professional information as approved by the Authority: 07 July 2006

Namibia: NS0 13/10.1/0094