1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

FLUTEX COUGH MIXTURE HONEY (syrup)

COMPOSITION

Each 5 ml FLUTEX COUGH MIXTURE HONEY contains 100 mg of guaiphenesin.

Excipients:

Dye Lennon brown (C.I. 48000), dye Lennon yellow (C.I. 47005) or colour spectracol quinoline yellow (C.I. 47005), flavour honey, glycerol, hydroxyethylcellulose, povidone K25, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium saccharin, sorbitol (70 %) solution

Preservative:

Sodium benzoate 0,1 % *m/v*

Contains sugar: Sorbitol (70 %) solution 1,25 ml

Contains sweetener: Sodium saccharin 25,00 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

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

CONTRAINDICATIONS

FLUTEX COUGH MIXTURE HONEY is contraindicated in:

- Hypersensitivity to any of the ingredients.
- Pregnancy and lactation.
- 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 secretions except on advice and under 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

FLUTEX COUGH MIXTURE HONEY contains sorbitol and may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take FLUTEX COUGH MIXTURE HONEY.

INTERACTIONS

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

HUMAN REPRODUCTION

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

DOSAGE AND DIRECTIONS FOR USE

Adults and children 12 years and over:

Take 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.

Children 6 to 12 years:

Take 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.

Children 2 to 6 years:

Take 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 pain

Frequency unknown: Discomfort

Skin and subcutaneous tissue disorders

Less frequent: Rash, urticaria

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Treatment

Treatment is symptomatic and supportive (see SIDE EFFECTS).

IDENTIFICATION

A clear, brownish-yellow, slightly viscous liquid.

PRESENTATION

50 or 100 ml are packed in an amber glass bottle with a white duet tamper evident polifin polypropylene screw cap.

50 or 100 ml are packed in an opaque, white high density polyethylene bottle with a white low

density snap on cap.

50 or 100 ml are packed in a flint glass bottle with a duet tamper proof cap.

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

A38/10.1/0358

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

PHARMACARE LIMITED

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