1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

FLUTEX COUGH MIXTURE ORANGE (syrup)

COMPOSITION

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

Excipients:

Citric acid monohydrate, dye Lennon Yellow (C.I. 15985) or colour Spectracol Sunset Yellow (C.I. 15985), flavour sweet orange essence, glycerol, hydroxyethylcellulose, povidone, propylene glycol, sodium benzoate, sodium chloride, sodium citrate dihydrate, sodium saccharin, sorbitol solution

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

Contains sugar: Sorbitol solution 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

Alleviation of cough associated with viscid/tenacious phlegm.

CONTRAINDICATIONS

- Hypersensitivity to any of the ingredients.
- Pregnancy and lactation.
- Contraindicated in 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 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.

Effects on ability to drive and use machines

FLUTEX COUGH MIXTURE ORANGE may cause dizziness and impair patients' reactions. Patients are advised not to drive or use machinery while taking FLUTEX COUGH MIXTURE ORANGE.

Excipients

Sorbitol warning:

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

INTERACTIONS

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

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

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.

Children 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.

Children 2 to 6 years: 50 mg to 100 mg 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

Symptoms

(see SIDE EFFECTS)

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

Clear, orange, slightly viscous liquid with an orange odour.

PRESENTATION

50 or 100 ml is packed in a round amber type III glass bottle, sealed with a white, cylindrical, polypropylene, tamper evident screw on cap with an expanded polyethylene liner. Each bottle will be placed in a unit carton.

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

50 or 100 ml is packed in a round flint type III glass bottle, closed with a white, cylindrical, polypropylene, tamper evident screw on cap with an expanded polyethylene 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

A38/10.1/0359

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

PHARMACARE LIMITED

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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: 23 March 2015

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