SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

FLUTEX COUGH MIXTURE BLACKCURRANT (syrup)

COMPOSITION

Each 5 ml FLUTEX COUGH MIXTURE BLACKCURRANT contains 100 mg guaiphenesin.

Excipients:

Dye blackcurrant, flavour blackcurrant, glycerol, hydroxyethylcellulose, povidone, purified water, propylene glycol, sodium benzoate, sodium chloride, sodium saccharin, sorbitol solution

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

Contains sugar: Sorbitol solution 1,30 g

Contains sweetener: Sodium saccharin 25,0 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 BLACKCURRANT is indicated for the alleviation of cough associated with viscid/tenacious phlegm.

CONTRAINDICATIONS

FLUTEX COUGH MIXTURE BLACKCURRANT is contraindicated in:

- Hypersensitivity to any of the ingredients (see COMPOSITION).
- 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 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 FLUTEX COUGH MIXTURE BLACKCURRANT.

INTERACTIONS

FLUTEX COUGH MIXTURE BLACKCURRANT interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid.

HUMAN REPRODUCTION

The safety of FLUTEX COUGH MIXTURE BLACKCURRANT 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.

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.

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 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 (see SIDE EFFECTS).

IDENTIFICATION

Clear, purple, slightly viscous liquid.

PRESENTATION

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

50 ml or 100 ml is packed into an opaque white high density polyethylene bottle with a white low density polyethylene snap on cap. Each bottle is placed in a unit carton.

50 ml or 100 ml is packed in a flint glass bottle with a white polypropylene tamper evident duet screw cap with a liner. Each bottle is 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

A38/10.1/0360

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

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SUID AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S0

EIENDOMSNAAM EN DOSEERVORM

FLUTEX COUGH MIXTURE BLACKCURRANT (stroop)

SAMESTELLING

Elke 5 ml FLUTEX COUGH MIXTURE BLACKCURRANT bevat 100 mg guajafenesien.

Eksipiënte:

Swartbessie kleursel, swartbessie geursel, gliserol, hidroksiëtielsellulose, povidoon, gesuiwerde water, propileenglikol, natriumbensoaat, natriumchloried, natriumsakkarien, sorbitol oplossing

Preserveermiddel: Natriumbensoaat 0,1 % *m/v*

Bevat suiker: Sorbitol oplossing 1,30 g

Bevat versoeter: Natriumsakkarien 25,0 mg

Alkoholvry

KATEGORIE EN KLAS

A 10.1 Hoesonderdrukkers en ekspektorante

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Guajafenesien is ’n ekspektorant wat die volume van hardnekkige sputum verhoog en die viskositeit daarvan verlaag.

Farmakokinetiese eienskappe

Guajafenesien word uit die spysverteringskanaal geabsorbeer. Dit word gemetaboliseer en in die urine uitgeskei.

INDIKASIES

FLUTEX COUGH MIXTURE BLACKCURRANT word aangedui vir die verligting van hoes wat met taai/hardnekkige slym verband hou.

KONTRA-INDIKASIE

FLUTEX COUGH MIXTURE BLACKCURRANT word teenaangedui by:

- Hipersensitiwiteit vir enige van die bestanddele (sien SAMESTELLING).
- Swangerskap en laktasie.
- Kinders onder 2 jaar oud.
- Porfirie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

- Moenie neem vir aanhoudende hoes soos dié wat voorkom met rook, asma, emfiseem, of waar hoes met uitermatige afskeidings gepaardgaan nie, behalwe op advies en onder toesig van ’n dokter.
- ’n Aanhoudende hoes kan ’n teken van ’n ernstige toestand wees. Indien hoes vir langer as een week voortduur, geneig is om terug te keer of met hoë koors, uitslag of aanhoudende hoofpyn gepaardgaan, raadpleeg ’n mediese praktisyn.

Eksipiënte

Bevat sorbitol en kan ’n lakserende effek hê.

Pasiënte met die seldsame oorerflike toestand van sorbitol onverdraagsaamheid moenie FLUTEX COUGH MIXTURE BLACKCURRANT neem nie.

INTERAKSIES

FLUTEX COUGH MIXTURE BLACKCURRANT meng in met urientoetse vir 5-hidroksi-indoolasynsuur (5-HIAA) en vanillielmandeliensuur.

MENSLIKE VOORTPLANTING

Die veiligheid van FLUTEX COUGH MIXTURE BLACKCURRANT tydens swangerskap en laktasie is nie vasgestel nie (sien KONTRA-INDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes en kinders van 12 jaar en ouer:

Neem 200 mg tot 400 mg (10 ml tot 20 ml) mondeliks, elke 4 ure. Moenie 2 400 mg (120 ml) binne 24 ure oorskry nie.

6 tot 12 jaar:

Neem 100 mg tot 200 mg (5 ml tot 10 ml) mondeliks, elke 4 ure. Moenie 1 200 mg (60 ml) binne 24 ure oorskry nie.

2 tot 6 jaar:

Neem 50 mg tot 100 mg (2,5 ml tot 5 ml) mondeliks, elke 4 ure. Moenie 600 mg (30 ml) binne 24 ure oorskry nie, of soos voorgeskryf deur ’n mediese praktisyn.

NEWE-EFFEKTE

Senuweestelsel versteurings

Minder dikwels: Hoofpyn, duiseligheid

Frekwensie onbekend: Lomerigheid

Gastroïntestinale versteurings

Minder dikwels: Diarree, naarheid, braking, maagpyne

Frekwensie onbekend: Ongemak

Vel en onderhuidse weefsel versteurings

Minder dikwels: Uitslag, urtikarie

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Behandeling is simptomaties en ondersteunend (sien NEWE-EFFEKTE).

IDENTIFIKASIE

Deursigtige, pers, effens viskeuse vloeistof.

AANBIEDING

50 ml of 100 ml word verpak in ’n amberkleurige glasbottel met ’n wit, polipropileen, peuterverklikkende duetskroefdop. Elke bottel word in ’n eenheidskarton houer geplaas.

50 ml of 100 ml word verpak in ’n ondeursigtige wit, hoëdigtheidspoliëtileen bottel met ’n wit laedigtheidspoliëtileen aanknip dop. Elke bottel word in ’n eenheidskarton houer geplaas.

50 ml of 100 ml word verpak in ’n flintglasbottel met ’n wit, polipropileen peuterverklikkende duetskroefdop met ’n voering. Elke bottel word in ’n eenheidskarton houer geplaas.

Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C in diggeslote houers.

Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

A38/10.1/0360

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

Datum van registrasie: 07 Julie 2006

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 07 Julie 2006

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