Skeduleringstatus S2

Eiendomsnaam en doseervorm

Pholtex® Junior, stroop

Samestelling
Elke 5 ml bevat: Folkodien 5 mg
Preserveermiddel: Metielhidroksibensoaat 0.1% m/v
Ander bestanddele sluit anhidriese sitroensuur, Gelcarin DG 5250, lemoengeur, gesuiwerde water en Sunset Yellow in.
Bevat Suiker: Sorbitol Oplossing 0,65 g/5ml
Bevat versoeter: Natriumsakkarien 1,5 mg/5ml

Farmakologiese klassifikasie
A. 10.1 Hoesonderdrukkers en ekspektoreermiddels

Farmakologiese werking
Folkodien is 'n hoesonderdrukker.

Indikasies
Vir die verligting van onproduktiewe hoes.

Kontra-indikasies
Intoleransie teenoor, of hipersensitiwiteit vir Folkodien of enige bestanddeel.
Swangerskap en laktasie.
Kinders onder die ouderdom van 2 jaar.

Waarskuwings
Folkodien moet met versigtigheid gebruik word in pasiënte met verminderde respiratoriese reserwe. Folkodien onderdruk die respiratoriese sentrum gering en moet versigtig in asmalyers gebruik word.

Aangesien Folkodien in die lewer metaboliseer word, kan lewer-ontoereikendheid die aksie verleng. Dit mag nodig wees om die dosis en frekwensie daarvan te verminder in pasiënte met verswakte lewerfunksie.

Bevat sorbitol wat 'n uitwerking op glukemiese beheer van pasiënte met diabetes mellitus kan hê.

Pasiënte met die seldsame oorerflike toestand van sorbitol intoleransie moet nie PHOLTEX JUNIOR neem nie.

Dosis en gebruiksaanwysings
Kinders 5-12 jaar: 2,5 tot 5 ml (half tot een medisynemaat) drie tot vier keer per dag.
2-5 jaar: 2,5 ml ('n halwe medisynemaat) drie keer per dag.
Nie geskik vir kinders onder die ouderdom van 2 jaar.

Newe-effekte en spesiale voorsorgmaatreëls
Duiseligheid, naarheid en braking kom af en toe voor. Na groot dosisse mag lomerigheid, rusteloosheid, opwinding, ataksie en respiratoriese depressie aangetref word.

Bekende simptome van oordosering en besonderhede van die behandeling daarvan
Simptome sluit duiseligheid, rusteloosheid, opwinding, ataksie en respiratoriese depressie in.
Behandeling is simptomaties. Ventilasie mag benodig word.

Identifikasie
'n Effens geel-oranje, belugte jel met 'n lemoen-geur.

Aanbieding
100 mℓ en 200 mℓ amber glas of PET bottels met 'n plastiek doppie.

Bergingsaanwysings
Bewaar teen of benede 30 °C
HOU BUITE BEREIK VAN KINDERS.

Registrasienommer
29/10.1/0013

Naam en besigheidsadres van die applikant
iNova Pharmaceuticals (Edms) Bpk
Rileyweg 15e, Bedfordview

Datum van publikasie van hierdie voubiljet
24 Februarie 2004

Pro-Print

Scheduling Status S2

Proprietary name and dosage form

Pholtex® Junior, syrup

Composition
Each 5 ml contains: Pholcodine 5 mg
Preservative: Methyl hydroxybenzoate 0.1% m/v
Other Ingredients are, citric acid anhydrous, Gelcarin DG 5250, orange flavour, purified water and sunset yellow.
Contains sugar: Sorbitol solution 0,65g/5ml
Contains sweetener: Saccharin sodium 1,5mg/5ml

Pharmacological classification
A. 10.1 Antitussives and Expectorants

Pharmacological action
Pholcodine is a cough suppressant.

Indications
For the relief of unproductive coughs.

Contraindications
Intolerance or hypersensitivity to Pholcodine or any of the ingredients.
Pregnancy and lactation.
Children under 2 years.

Warnings
Pholcodine should be used with caution in patients who have decreased respiratory reserve. Pholcodine depresses the respiratory center to some extent and should be used with caution in asthmatics.

Since Pholcodine is metabolised in the liver, its action may be prolonged in hepatic insufficiency. The dosage and frequency of administration may need to be reduced in patients with impaired liver function.

Contains sorbitol which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary condition of sorbitol intolerance should not take PHOLTEX JUNIOR.

Dosage and directions for use
Children 5-12 years: 2,5 to 5 ml (half to one medicine measure) three to four times a day.
2-5 years: 2,5 ml (half a medicine measure) three times a day.
Not suitable for children under 2 years of age.

Side effects and special precautions
Dizziness, nausea and vomiting occasionally occur. After large doses, drowsiness, restlessness, excitement, ataxia and respiratory depression may occur.

Known symptoms of overdosage and particulars of its treatment
Symptoms include drowsiness, restlessness, excitement, ataxia and respiratory depression. Treatment is symptomatic. Ventilation may be required.

Identification
A slightly cloudy yellow-orange aerated gel with an odour of orange.

Presentation
100 mℓ or 200 mℓ amber glass or PET bottles fitted with a plastic cap.

Storage instructions
Store at or below 30 °C
KEEP OUT OF REACH OF CHILDREN.

Registration number
29/10.1/0013

Name and business address of applicant
iNova Pharmaceuticals (Pty) Ltd
15e Riley Road, Bedfordview

Date of publication of this package insert
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NAMIBIA	
Scheduling status	: NS1
Registration number	: 04/10.1/0959

BOTSWANA	
Scheduling status	: 1D
Registration number	: BOT 9700125

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