Scheduling status S2

Proprietary name and dosage form

Pholtex Forte Liquid

Composition
Each 5 ml contains: Pholcodine 15 mg
Preservative: Methyl hydroxybenzoate 0.1% m/v

Other excipients include apricot flavour (contains ethyl alcohol), citric acid anhydrous, Natrosol 250 HHX, purified water and sunset yellow.
Contains sugar: Sorbitol solution 1,75g/5ml
Contains sweetener: Saccharin sodium 1,5mg/5ml

Pharmacological classification
A.10.1 Antitussives

Pharmacological action
Pholcodine is a cough suppressant.

Indications
For the relief of unproductive coughs.

Contraindications
Hypersensitivity to pholcodine or any of the ingredients.
Pregnancy and lactation.
Refer to **Pregnancy and Lactation**.

Warnings and Special Precautions
Pholcodine should be used with caution in patients who have decreased respiratory reserve. Pholcodine depresses the respiratory centre 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 glycemic control of patients with diabetes mellitus.
Patients with the rare hereditary condition of sorbitol intolerance should not take PHOLTEX FORTE.

Pregnancy and Lactation
Pregnancy
PHOLTEX FORTE is contraindicated in pregnancy. Refer to **Contraindications**.
Lactation
PHOLTEX FORTE is contraindicated in lactation. Refer to **Contraindications**.

Dosage and directions for use
Adults: 5 ml (one medicine measure) two to three times a day.
Children: 5-12 years: Up to 2.5 ml (half a medicine measure) two to three times a day.
Do not exceed the stated dose.
Shake the bottle before use.

Side effects
Dizziness, nausea and vomiting may 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 clear yellow-orange, slightly viscous liquid with an odour of apricot.

Presentation
100 mℓ and 200 mℓ amber plastic or amber glass bottles with a white tamper evident cap.

Storage instructions
Store at or below 30 °C
Keep well closed
KEEP OUT OF REACH OF CHILDREN

Registration number
32/10.1/0116

BOTSWANA	
Scheduling status:	3
Pharmacological classification:	ATC: R05D A08 Cough suppressant; opium alkaloids and derivatives
Registration Number:	BOT 0200484

ZIMBABWE	
Category of distribution:	Pharmacy Initiated Medicine (PIM)
Registration Number:	99/22.2.1.3624

NAMIBIA	
Scheduling status	: NS1
Registration Number	: 04/10.1/0958

Name and business address of applicant
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inova pharmaceuticals

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Skeduleringstatus S2

Eiendomsnaam en doseervorm

Pholtex Forte Vloeistof

Samestelling
Elke 5 ml bevat: Folkodien 15 mg
Preserveermiddel: Metielhidroksibensoaat 0.1% m/v

Ander bestanddele sluit appelkoosgeur 01-2500 (bevat etielalkohol), anhidriese sitroensuur, Natrosol 250 HHX, gesuiwerde water en Sunset Yellow in.
Bevat Suiker: Sorbitol Oplossing 1,75 g/5ml
Bevat versoeter: Natriumsakkarien 1,5 mg/5ml

Farmakologiese klassifikasie
A.10.1 Hoesonderdrukkers

Farmakologiese werking
Folkodien is 'n hoesonderdrukker.

Indikasies
Vir die verligting van onproduktiewe hoes.

Kontra-indikasies
Hipersensitiwiteit vir folkodien of enige van die bestanddele.
Swangerskap en laktasie. Verwys na **SWANGERSKAP EN LAKTASIE**.

Waarskuwings en Spesiale Voorsorgmaatreëls
Folkodien moet met versigtigheid gebruik word in pasiënte met verminderde respiratoriese reserwe.
Folkodien onderdruk die respiratoriese sentrum gering en moet met versigtigheid gebruik word in asmalyers.
Aangesien folkodien deur die lewer gemetaboliseer word, mag lewerontoereikendheid die aksie verleng. Dit mag nodig wees om die dosis en frekwensie van toediening te verminder in pasiënte met 'n 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 FORTE neem nie.

Swangerskap en Laktasie
Swangerskap
PHOLTEX FORTE is gekontra-indikeer tydens swangerskap. Verwys na **Kontra-indikasies.**

Laktasie
PHOLTEX FORTE is gekontra-indikeer tydens laktasie. Verwys na **Kontra-indikasies.**

Dosis en Gebruiksaanwysings
Volwassenes: 5 ml (een medisynemaat) twee tot drie keer per dag.
Kinders: 5 - 12 jaar: Tot 2.5 ml ('n halwe medisynemaat) twee tot drie keer per dag.
Moet nie die gegewe dosis oorskry nie.
Skud bottel voor gebruik.

Newe Effekte
Duiseligheid, naarheid en braking mag voorkom. Na groot dosisse mag lomerigheid, rustelоosheid, opwinding, ataksie en respiratoriese onderdrukking voorkom.

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

Identifikasie
'n Helder, effens viskeuse vloeistof met 'n appelkoos geur.

Aanbieding
100 mℓ en 200 mℓ amber plastiek of amber glas bottels met 'n wit peuter-bestande plastiek doppie.

Bergingsaanwysings
Bewaar teen of benede 30 °C
Hou styf toegedraai
HOU BUITE BEREIK VAN KINDERS

Registrasienommer
32/10.1/0116

Naam en besigheidsadres van die applikant
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