1.3.1.1 Professional Information

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

PHOLTEX FORTE, pholcodine 15 mg/5 ml liquid.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains: Pholcodine 15 mg

Preservative: Sodium benzoate 0,2 % *m/v*

Contains sugar: Sorbitol solution 1,75 g/5 ml.

Contains sweetener: Saccharin sodium 0,75 mg/5 ml.

For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

A clear yellow-orange, slightly viscous liquid with an odour of apricot.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

For the relief of unproductive coughs.

4.2 Posology and method of administration

Adults: 5 ml (one medicine measure) two to three times a day.

Children 5 – 12 years: 2,5 ml (half a medicine measure) two to three times a day.

Do not exceed the recommended dose.

4.3 Contraindications

Pholtex Forte should not be given to patients with or at risk of developing respiratory failure as the sedative properties of pholcodine may exacerbate the condition.

Patients with chronic bronchitis, COPD, bronchiolitis or bronchiectasis due to sputum retention.

Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment (see 4.5).

Patients with hypersensitivity or idiosyncratic response to pholcodine or to any of the excipients.

Patients with liver disease since pholcodine is metabolised in the liver and the drug may accumulate.

Children under two years of age.

Pregnancy and lactation. Refer to 4.6.

4.4 Special warnings and precautions for use

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.

Use of pholcodine with alcohol or other central nervous system (CNS) depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

Severe cutaneous adverse reactions (SCARs) including acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in patients treated with pholcodine, most likely in the first week. Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, this medicine should be withdrawn immediately.

Contains sorbitol which may have an effect on the glycaemic control of patients with *diabetes mellitus.* Medicines containing sorbitol may have a laxative effect. Patients with the rare hereditary condition of sorbitol intolerance should not take Pholtex Forte.

4.5 Interaction with other medicines and other forms of interaction

The reduction in blood pressure caused by antihypertensives may accentuate the hypotensive effects of pholcodine. Diuretics may have a similar effect. The sedative effects of central nervous system depressants may be increased by alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers (phenothiazines and tricyclic antidepressants). Hypertensive crisis may be caused by concurrent use of pholcodine with monoamine – oxidase inhibitors therefore not to be used in patients taking MAOIs or within 14 days of stopping treatment.

Interaction with neuromuscular blocking agents (anaphylaxis) has been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

PHOLTEX FORTE is contraindicated in pregnancy. Refer to 4.3.

Breastfeeding

PHOLTEX FORTE is contraindicated in lactation. Refer to 4.3.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Pholcodine may cause drowsiness and dizziness. Patients receiving this medication should not drive or operate machinery unless it has been shown not to affect mental or physical ability.

4.8 Undesirable effects

Immune system disorders

Frequency unknown: hypersensitivity reactions, anaphylaxis.

Nervous system disorders

Frequency unknown: Dizziness, drowsiness, confusion, excitation, restlessness, ataxia and respiratory depression.

Gastrointestinal disorder

Frequency unknown: Constipation, vomiting, nausea, sputum retention.

Skin and subcutaneous tissue disorder

Frequency unknown: Skin reactions including rash, acute generalized exanthematous pustulosis. (See 4.4).

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8publications: Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

Website: www.inovapharma.co.za.

4.9 Overdose

Symptoms include drowsiness, restlessness, excitement, ataxia and respiratory depression. Ventilation may be required.

Management: Treatment of overdose should be symptomatic and supportive. Naloxone has been used successfully to reverse central or peripheral opioid effects in children (0.01 mg/kg body weight). Other treatment option is activated charcoal (1 g/kg body weight) if more than 4 mg/kg has been ingested within 1 hour, provided the airway can be protected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.10.1 Antitussives and Expectorants.

Pholcodine is a cough suppressant.

Morphine or codeine derivative. By tradition used mainly as an antitussive. It suppresses the cough reflex by a direct central action, probably in the medulla or pons. It has little or no analgesic or euphorigenic activity. It is metabolised by the liver.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Apricot flavour 01-2500 (contains ethyl alcohol)
- Citric acid anhydrous
- Disodium edetate
- Natrosol 250 HHX (hydroxyethyl cellulose)
- Purified water
- Saccharin sodium
- Sodium citrate dehydrate
- Sorbitol solution
- Sunset yellow.

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 30 °C. Keep well closed.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Limited

15E Riley Road

Bedfordview

South Africa

8 REGISTRATION NUMBER

32/10.1/0116

9 DATE OF FIRST REGISTRATION

26 February 1999

10 DATE OF REVISION OF THE TEXT

20 May 2022