NEW ZEALAND DATASHEET

1 NAME OF THE MEDICINE

Pholcodine Linctus BP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL contains pholcodine 5 mg.

For full list of excipients, see Section 6.1 List of excipients.

3 PHARMCEUTICAL FORM

Pholcodine Linctus BP is a clear colourless solution.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For relief of a dry, non-productive cough

4.2 DOSE AND METHOD OF ADMINISTRATION

Dosage: For oral administration

Adults and children over 12 years

10 mL up to six times daily. Dosage should be reduced in elderly or weak patients.

Children 6 – 12 years

5 mL up to four times daily. For children 6-12 years, it is recommended to seek advice from a healthcare professional before use.

Must not be used in children under 6 years of age.

4.3 CONTRAINDICATIONS

Patients in or at risk of developing respiratory failure or during an asthma attack, 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.

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.

Patients with ventilatory failure.

Children under 6 years of age.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Should be used with caution by patients with liver or renal impairment.
- Ask a doctor before use if you suffer from a chronic or persistent cough, if you have asthma, suffering from acute asthma attack or where cough is accompanied by excessive secretions.
- Do not take with any other cough and cold medicine.
- Sunset yellow (in Pholcodine Linctus BP) may cause allergic reactions
- Use of Pholcodine with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.
- Children and elderly patients should be supervised while taking this medication.
- Caution is needed in patients with a history of drug abuse. Pholcodine is an opioid and addiction is observed with opioids as a class.
- 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.
- Serious allergic reactions (anaphylaxis) have been reported with exposure to neuromuscular blocking agents (NMBAs) in patients who have previously taken pholcodine. Cross-reactivity between pholcodine and NMBAs may lead to sensitisation to NMBAs. Patients and healthcare professionals should be aware that taking pholcodine may increase the risk of a serious allergic reaction in the future if they require an anaesthetic procedure involving a NMBA.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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

This product should not be used during pregnancy or lactation unless it is considered essential by the physician.

Risk – benefit must be considered before using pholcodine during pregnancy or lactation. Opioid analgesics cross the placenta. Regular use during pregnancy may cause physical dependency and respiratory difficulties in the foetus, leading to withdrawal symptoms in the neonate, particularly in the premature neonate. There is a risk of gastric stasis in the

mother during labour which may lead to inhalation pneumonia. Teratogenic effects in humans have not been documented but controlled studies have not been done, nor have studies in animals been documented for pholcodine. Although it is known that some opioid analgesics are excreted in breast milk, information on the excretion of pholcodine in breast milk is lacking.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Pholcodine may cause drowsiness. 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

The following side effects may be associated with the use of pholcodine:

Nervous system disorders

Occasional drowsiness, dizziness, excitation, confusion

Respiratory, thoracic and mediastinal disorders

Sputum retention

Gastrointestinal disorders

Vomiting, gastrointestinal disturbances (nausea and constipation)

Skin and subcutaneous tissue disorders

Skin reactions including rash

Immune system disorders

Hypersensitivity reactions and anaphylaxis.

Skin and subcutaneous tissue disorders

Unknown: Acute generalized exanthematous pustulosis

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 OVERDOSE

It is thought to be of low toxicity but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs. A toxic dose in children is reported to be about 200 mg.

Symptoms: These include nausea, drowsiness, restlessness, excitement, ataxia and respiratory depression.

Management: Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use. 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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Morphine or codeine derivatives. 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 in the liver.

5.2 PHARMACOKINETIC PROPERTIES

The duration of action is 4-5 hours. Pholcodine is metabolized in the liver.

5.3 PRECLINICAL SAFETY DATA

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Carmellose

Citric acid monohydrate

Propylene glycol

Purified water

Saccharin sodium

Sodium benzoate

Sorbitol

Sunset yellow FCF

6.2 INCOMPATIBILITIES

No data available

6.3 SHELF LIFE

48 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25 °C.

7 MEDICINE SCHEDULE

Pharmacist only medicine

8 SPONSOR

AFT Pharmaceuticals Ltd.

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9 DATE OF FIRST APPROVAL

13 October 2022