

CORE PHOLCODINE PRODUCT INFORMATION

Product description

This section should include:

- a description of the dosage form;
- a list of the active ingredients expressed quantitatively; and
- a list of the excipients expressed qualitatively

Pharmacology

Pharmacokinetics:

Pholcodine is readily absorbed from the gastrointestinal tract and freely crosses the blood-brain barrier. It is metabolised in the liver and its action may be prolonged in hepatic insufficiency.

Pharmacodynamics/Mechanism of action:

Pholcodine is a cough suppressant that acts primarily on the central nervous system (CNS) causing depression of the cough reflex, partly by a direct effect on the cough centre in the medulla. It also has a mild sedative effect.

Pholcodine has little or no analgesic action.

Therapeutic doses of pholcodine do not cause depression of respiration, CNS excitation or other side effects associated with narcotics. Pholcodine has a selective effect on the cough centre without affecting the respiratory centre.

Pholcodine is not euphorogenic, therefore psychological dependence is unlikely to be a problem. There is no evidence of physical dependence after prolonged administration of pholcodine so it is not likely to be habit forming.

Indications

This section must contain the indications of the product as specified in the ARTG. If the indications are not specified in the ARTG (e.g. for a non-validated grandfathered product), the indications must be as specified on the product label.

Contraindications

Pholcodine is contraindicated for use in patients:

- with known hypersensitivity or idiosyncratic reaction to pholcodine, (or any of the other ingredients in the product);
- at risk of developing respiratory failure.

Refer to 'Interactions with other medicines' for additional information

Precautions

Pholcodine should be used with caution in patients with a history of asthma.

Refer to 'Interactions with other medicines' for additional information

Use in pregnancy

Category A: Pholcodine has been taken by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Lactation

It is not known whether pholcodine is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

Interaction with other medicines

Concomitant use of pholcodine with central nervous system depressants (e.g. sedatives, alcohol) may increase the depressant effects on the central nervous system.

Adverse reactions

Adverse events are rare and may include dizziness and gastrointestinal disturbances such as nausea or vomiting. Adverse effects such as constipation, drowsiness, excitation, ataxia and respiratory depression have been reported occasionally or after large doses.

Dosage

This section must contain the current dosage instructions of the registered product, as specified on the product label.

Overdosage

In case of overdose, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice.

Presentation

Information should be included on:

- *the presentation, including dosage form and pack sizes;*
- *identifying details (eg. colour, shape, identifying markings);*
- *poisons schedule details; and*
- *name and address of the sponsor.*

Include the date of approval as the date on which the notification application is lodged