Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pholcodex 5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 5 mg Pholcodine.

Excipients with known effect:
Sunset yellow (E110) 0.375 mg/5 ml
Sorbitol solution (E420) 651.0 mg/5 ml
Sodium benzoate (E211) 6 mg/5 ml
Sodium 6.38 mg/5 ml
Propylene glycol 93 mg/5 ml

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Oral solution
Clear, yellow oral solution with a citrus flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of non-productive cough. This product is indicated for second line use only.

4.2 Posology and method of administration

Posology

Adults: 10 ml every three to four hours as required

Paediatric posology

Children (Aged 6-12 years): 5 ml every three to four hours as required

Method of administration
For oral administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Use in children under 6 years of age.

4.4 Special warnings and precautions for use

1. Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose.
2. Do not take with any other cough and cold medicine.
3. Consult a pharmacist or other healthcare professional before using this medicine.
4. Side effects include occasional nausea and drowsiness.
5. This product should only be used for suppression of a non-productive cough.
6. Cough suppressants may depress respiration and should be used with caution in patients with asthma, chronic bronchitis or bronchiectasis.
7. Special care should be taken in patients with renal or hepatic impairment.

8. The use of this product should be restricted to no more than 5 days.
9. This product should only be indicated for second line use.
10. 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 If signs and symptoms suggestive of these reactions appear, this medicine should be withdrawn immediately.
11. Caution is needed in patients with a history of drug abuse. Pholcodine is an opioid and addiction is observed with opioids as a class.
12. Cross-reactivity leading to serious allergic reactions (anaphylaxis) have been reported between pholcodine and NMBAs (Neuromuscular Blocking Agents). A precise at-risk period of time between the exposures of pholcodine and NMBAs has not been determined. Clinicians should be aware of this potential in case of future anaesthetic procedures involving NMBAs.

Excipients: Sorbitol, Sunset yellow, Sodium benxoate, Propylene glycol and Sodium.

Sorbitol
This medicine contains 651 mg of sorbitol solution per 5 ml dose. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Sunset yellow
Sunset yellow may cause allergic reactions.

Sodium benzoate
This medicine contains 6 mg sodium benzoate in each 5 ml which is equivalent to 1.2 mg/ml.

Propylene glycol
This medicinal product contains 93 mg propylene glycol in 5 ml which is equivalent to 18.6 mg/ml.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

Pholcodine may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

4.6 Fertility, pregnancy and lactation

Pregnancy
This product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

This product may induce 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

System organ class	Frequency	Adverse reaction
Nervous system disorders:	Common	Drowsiness
Gastrointestinal disorders	Common	Nausea,
Skin and subcutaneous tissue disorders	Unknown	Acute generalized exanthematous pustulosis (AGEP) (see section 4.4)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance Website: www.hpra.ie

4.9 Overdose

Management:
If an overdose with Pholcodine does occur, supportive therapy is recommended. In the event of serious overdose gastric lavage may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code – R05DA08

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.

5.2 Pharmacokinetic properties

Usual dosage: 10-15 mg.
Duration of action: 4-5 hours.

5.3 Preclinical safety data

Not appropriate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Saccharin sodium
Propylene glycol
Sodium benzoate (E211)
Carmellose sodium (E466)
Sunset yellow (E110)
Sorbitol solution 70% (E420)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container protected from light.

6.5 Nature and contents of container

Amber glass bottles with polypropylene (PP) tamper-evident (T/E) child resistant caps (CRCs) containing 100ml, 125ml, 150ml or 200ml.
Not all pack sizes may be marketed.
Measuring device: polypropylene measuring spoon.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Ltd,

Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0281/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 June 1980

Date of last renewal: 04 June 2010

10 DATE OF REVISION OF THE TEXT

May 2022