SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hill's Balsam Dry Cough Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pholcodine 10 mg/5 ml.

Excipients with known effect

Each 5ml also contains 3.5 mg sodium methyl hydroxybenzoate, 1.5 mg sodium propyl hydroxybenzoate, 195 mg ethanol and 2.67 g sucrose.

Each 5 ml contains 0.63 mg (0.027 mmol) sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Brown, viscous, oral solution with aromatic odour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of a dry, tickly or painful unproductive cough due to upper respiratory infection or influenza.

4.2 Posology and method of administration

Posology

Paediatric population

Hill's Balsam Dry Cough Liquid is contraindicated in children under 12 years of age (see section 4.3).

Adults and children over 12 years:

One 5ml spoonful to be taken three times a day and at bedtime (in a little warm water).

Method of administration

For oral use

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

History of allergy toward morphine, suxamethonium or other structurally related therapeutic agents.

Liver failure.

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

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 section 4.5).

Children under 12 years of age.

4.4 Special warnings and precautions for use

Use with caution in patients with respiratory disease, including a history of asthma.

Pholcodine may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis.Use with caution in patients with renal or hepatic disease.

Caution is also needed in patients with a history of drug abuse.

Pholcodine should not be taken with any other cough or cold medicine (see section 4.5).

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Use of Pholcodine with alcohol or other CNS depressants may increase the effect on the CNS. Which may lead to greater drowsiness and sedation.

Pholcodine should not be taken with any other cough or cold medicine.

Not to be used in patients taking MAOIs or within 14 days of stopping treatment.

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

Pholcodine may accentuate the hypotensive effects of antihypertensives. The same effect may be seen when administered with diuretics.

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

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no data available

Hill's Balsam Dry Cough Liquid should not be used in pregnancy unless considered necessary by the physician and the expected benefit is thought to outweigh any possible risk to the foetus. It should be avoided during the first trimester.

Breastfeeding

Pholcodine has been detected in human breastmilk. Although the amount is unlikely to affect the suckling infant the use of Hill's Balsam Dry Cough Liquid during lactation is not recommended.

4.7 Effects on ability to drive and use machines

As with other opioid, pholcodine may affect the ability to drive or use machines.

The use of pholcodine may cause sedation, dizziness and nausea. If affected, driving or operation of machinery would not be advised.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine
- However, you would not be committing an offence (called 'statutory defence') if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and
  - o It was not affecting your ability to drive safely.

4.8 Undesirable effects

The following adverse effects may be associated with the use of pholcodine:
(frequencies not known and cannot be estimated from the available data)

Gastrointestinal disorders

Nausea and vomiting occasionally occurs after pholcodine administration. Although pholcodine may cause constipation, this is far less likely than with some of the other opioid analgesics such as codeine.

Immune system disorders

Hypersensitivity reactions, anaphylaxis.

Nervous system disorders

Occasional drowsiness, dizziness.

Psychiatric disorders

Excitation, confusion.

Respiratory, thoracic and mediastinal disorders

Sputum retention.

Skin and subcutaneous disorders

Skin reactions including rash.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Pholcodine is thought to be of low toxicity but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms of overdose include respiratory depression, restlessness, excitement, ataxia, nausea and drowsiness.

Treatment should be symptomatic to maintain vital functions. Respiratory distress and shock should be treated by supportive means. Airways protective gastric lavage may be of use.

In severe cases a specific antagonist such as naloxone may be considered. Naloxone has been used successfully to reverse central or peripheral opioid effects in children (0.01 mg/kg body weight).

Another treatment option is activated charcoal (1g/kg body weight) if more than 4 mg/kg has been ingested within 1 hour, provided the airway can be protected. Charcoal has been shown to be effective in reducing absorption in volunteers for up to 2 hours after ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Opium alkaloids and derivatives. ATC code: R05DA08

Pholcodine is widely used in the treatment of dry unproductive cough. Pholcodine is a centrally acting cough suppressant and can relieve local irritation of the respiratory tract for about 4 to 5 hours. Pholcodine has less sedatory and depressant effects on respiration when compared with morphine.

5.2 Pharmacokinetic properties

Pholcodine is well absorbed from the gastro-intestinal tract and is metabolised in the liver.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

Sodium methyl hydroxybenzoate (E219)

Sodium propyl hydroxybenzoate (E217)

Hydroxyethylcellulose

Treacle

Special flavour NI 225892

Capsicum tincture

Compound benzoin tincture

Ethanol (96%)

Anise oil

Peppermint oil

Sucrose

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Amber glass bottle with a child resistant closure.

Registered pack sizes of 100ml and 200ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Infohealth Laboratories Limited

28 Chipstead Valley Road

Coulsdon

Surrey

CR5 2RA

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00415/0201

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd February 2005

10 DATE OF REVISION OF THE TEXT

23/10/2015