

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pholcodex 5 mg/5 ml Oral Solution Pholcodine 5 mg/5 ml

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. This medicine is available from your pharmacy without prescription; however, you still need to take Pholcodex 5 mg/5 ml Oral Solution carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet:

1. What Pholcodex is and what it is used for
2. What you need to know before you take Pholcodex
3. How to take Pholcodex
4. Possible side effects
5. How to store Pholcodex
6. Contents of the pack and other information

1. What Pholcodex is and what it is used for

Pholcodex 5 mg/5 ml Oral Solution is a medicine which helps you to stop coughing, especially if you have a dry non-productive cough. It is related to morphine and codeine, and it acts to stop your automatic cough response. Pholcodex should only be taken when other treatments have failed.

2. What you need to know before you take Pholcodex

Do not take Pholcodex:

- if you are allergic (hypersensitive) to pholcodine or any of the other ingredients of this medicine (*listed in Section 6 and end of Section 2*).
- if you have:
 - liver disease.
 - breathing problems.
 - a hereditary intolerance to some sugars.
 - taken/given any other cough and cold medicine.
 - ever developed a severe skin rash or skin that peels, blisters and / or sores in the mouth after taking pholcodine.

Children under 6 years of age should not be given this medicine.

Take special care with Pholcodex if you have:

- asthma.
- kidney problems.
- a problem with drug abuse (now or in the past).
- chronic bronchitis or an obstruction in your lungs.
- are pregnant or breast-feeding.

Take care if giving Pholcodex to the elderly or to children. Supervision of these patients is advisable.

Warnings and precautions:

Serious skin reactions, including acute generalized exanthematous pustulosis (AGEP), have been reported with the use of pholcodine. AGEP is a generalized, red, scaly rash with bumps under the skin and vesicles associated with fever. Most common location: mainly located on the folds of the skin, the trunk and the upper limbs. The highest risk of serious skin reactions occurrence is especially during the first week of treatment. If you develop a severe rash or any of these skin symptoms, stop taking this medicine and contact or see a doctor immediately.

Consult a doctor before use if you have a history of drug abuse; pholcodine is an opioid and addiction is observed with opioids as a class.

Cases of cross-reactivity with medicines called muscle relaxants used during anaesthesia, resulting in serious allergic reactions (anaphylaxis) have been reported in patients who have previously taken pholcodine. If are due to undergo anaesthesia at any time (such as for surgery), please inform your anaesthetist that you have taken pholcodine in the past.

Other medicines and Pholcodex

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but especially the following:

- sedatives / tranquillisers (including sleeping tablets)
- pain killers
- drugs for epilepsy.

You must not consume alcohol while taking this medicine as this may increase drowsiness.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Regular or prolonged use of Pholcodex during pregnancy or breast-feeding may affect your baby, so follow the advice of your doctor or pharmacist.

Driving and using machines

Pholcodex may cause drowsiness. Do not drive or operate machinery until you know how the medicine will affect you.

Important information about some of the ingredients of Pholcodex

Pholcodex contains:

- **Sunset yellow (E110):** which may cause allergic reactions
- **Sorbitol solution (E420):** this medicine contains 651 mg sorbitol solution in each 5 ml spoonful which is equivalent to 130.2 mg/ml. Sorbitol is a source of fructose. If your

doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

- **Sodium benzoate (E211):** this medicine contains 6 mg benzoate salt in each 5 ml spoonful which is equivalent to 1.2 mg/ml.
- **Sodium:** this medicine contains less than 1 mmol sodium (23 mg) per 5 ml spoonful, that is to say essentially 'sodium-free'.
- **Propylene glycol:** 93 mg propylene glycol in each 5 ml spoonful, which is equivalent to 18.6 mg/ml.

3. How to take Pholcodex

You should check with your doctor or pharmacist before using this medicine. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Only to be taken by mouth. Please use measuring spoon provided.

The usual dose is:

Adults:	10 ml every three to four hours as required.
Children 6 - 12 years:	One 5 ml spoonful every three to four hours as required.

Not more than 4 doses should be given in any 24 hours. DO NOT exceed the stated dose. Do not take with any other cough and cold medicine. Not recommended for children under 6 years of age. Children should be supervised while taking this medicine. This product should not be used for more than 5 days.

If you take more Pholcodex than you should

If you or someone else takes too much Pholcodex, you should contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Pholcodex

If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced times. Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pholcodex can cause side effects, although not everybody gets them.

You should STOP using Pholcodex and seek advice from your doctor if you experience a rare allergic reaction, including skin rashes, increased sensitivity to light, inflammation of the blood vessels, fever or shock.

You may also notice the following more common side effects:

- nausea, vomiting, constipation
- drowsiness, dizziness
- skin reactions

- slow or shallow breathing
- difficulty in coughing up mucus or saliva
- excitation, confusion

Not known: frequency cannot be estimated from the available data

Generalized rash, red and scaly with bumps under the skin and vesicles associated with fever at the beginning of treatment (generalized acute exanthematous pustulosis). If you develop these symptoms stop using this medicine and contact or see a doctor immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pholcodex

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original container protected from light.

Do not use this medicine after the expiry date which is stated on the label or carton after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pholcodex contains:

- The active substance is Pholcodine 5 mg/5 ml.
- The other ingredients are citric acid monohydrate, saccharin sodium, propylene glycol, sodium benzoate (E211), carmellose sodium (E466), sunset yellow (E110), sorbitol (E420) and purified water. See end of Section 2.

What Pholcodex looks like and contents of the pack

Pholcodex is a clear yellow, oral solution, available in 200 ml, 150 ml, 125 ml and 100 ml amber glass bottles. All pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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