



Package leaflet: Information for the user
PHOLCODINE LINCTUS BP
Pholcodine BP 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 or nurse have told you.

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

1. What Pholcodine Linctus is and what it is used for

Pholcodine Linctus 5 mg/5 ml 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.

2. What you need to know before you take Pholcodine Linctus

It's normal for children to get 8 or more colds in a year. Because colds are caused by viruses, not bacteria, antibiotics don't help. Here are simple steps to help your child who has a cough or cold.

1. **If they are hot/feverish:** Increase the amount of fluid your child normally drinks. Lower their temperature with a paracetamol or ibuprofen medicine which has doses for children.
2. **For coughs:** Coughing serves a purpose, it helps clear phlegm and mucus. Give the child plenty of warm clear fluids to drink.
3. **To help with breathing:** Plain saline nose drops/sprays can help with blocked noses.

Do not take Pholcodine Linctus if you have:

- an allergy (hypersensitivity) to pholcodine or any of the other ingredients of Pholcodine Linctus (see Section 6 and end of Section 2).
- liver disease.
- breathing problems, chronic bronchitis, COPD or an obstruction in your lungs.
- 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 should not be given this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Pholcodine Linctus.

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 you are due to undergo anaesthesia at any time (such as for surgery), please inform your anaesthetist that you have taken pholcodine in the past.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Take special care with Pholcodine Linctus and talk to your doctor or pharmacist if you have/are:

- asthma.
- kidney problems.
- a persistent cough.
- a cough with excessive secretions.

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

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.

Other medicines and Pholcodine Linctus

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines especially the following:

- anti-depressants known as monoamine-oxidase inhibitors (MAOIs). Pholcodine should NOT be taken at the same time as or within 14 days of stopping MAOIs
- antihypertensives (for reducing blood pressure)
- water tablets (diuretics)
- medicines for mood disorders such as phenothiazines and tricyclic antidepressants
- CNS depressants e.g. hypnotics (sleeping tablets), tranquillisers, opioid analgesics (drugs for severe pain)
- neuromuscular blocking agents (anaesthetics used during surgery)

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you think you may be pregnant or are planning to have a baby, or if you are breast-feeding. Regular or prolonged use of Pholcodine Linctus during pregnancy or breast-feeding may affect your baby, so follow the advice of your doctor or pharmacist.

Driving and using machines

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

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Important information about some of the ingredients of Pholcodine Linctus

Pholcodine Linctus contains:

- **Sunset yellow (E110):** 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 Pholcodine Linctus

Always take the product exactly as advised. You should check with your doctor or pharmacist if you are not sure. Only to be taken by mouth.

The usual dose is:

Adults:	10 ml up to 6 times in any 24 hours.
Children aged 6 - 12 years:	5 ml up to 4 times in any 24 hours. Not to be given for more than 5 days without the advice of a doctor.
Elderly or weak patients:	Give a reduced dose; your doctor or pharmacist can advise you.
Do not give to children under 6 years of age	

Warning: Do not take more medicine than the label tells you to.

If you find that you need to take this medicine for a long time, or that the effect of the medicine becomes weaker, consult your doctor.

If your child's condition deteriorates while taking this medicine, medical attention should be sought.

If you take more Pholcodine Linctus than you should

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

If you forget to take Pholcodine Linctus

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 product, ask your doctor or pharmacist.

4. Possible side effects

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

STOP using Pholcodine Linctus and seek advice from your doctor if you experience a rare allergic reaction, including skin rashes, swollen face, lips, tongue, difficulty breathing, 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 including rashes
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pholcodine Linctus

Keep out of the sight and reach of children.

Do not use Pholcodine Linctus after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pholcodine Linctus contains:

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

What Pholcodine Linctus looks like and contents of the pack

Pholcodine Linctus is a clear orange viscous syrup, available in 2000 ml or 1000 ml plastic (HDPE) bottles, or in 200 ml, 125 ml and 100 ml amber glass bottles.

Marketing Authorisation Holder and Manufacturer

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

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