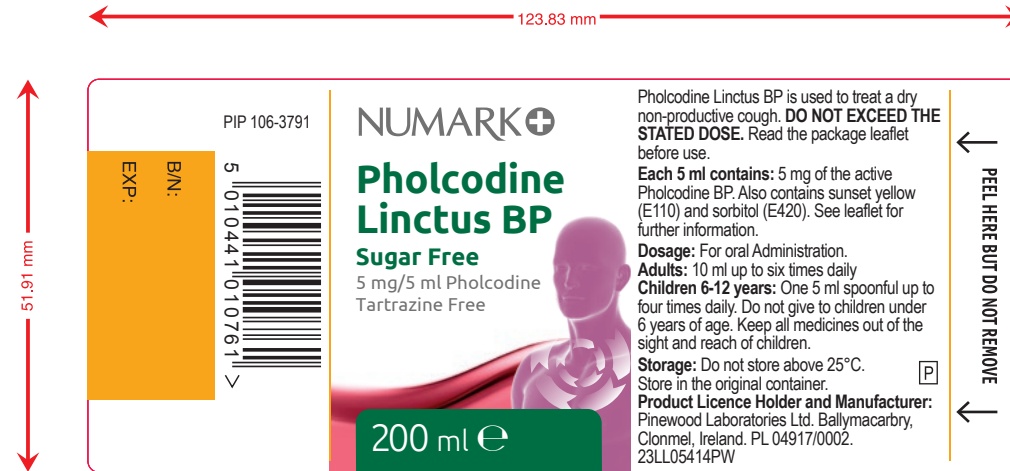


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PACKAGE LEAFLET: INFORMATION FOR THE USER**Pholcodine Linctus BP****Pholcodine BP 5 mg /5 ml****Read all of this leaflet carefully because it contains important information for you.**

This medicine is available from your pharmacy without prescription, however, you still need to take Pholcodine Linctus 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.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.
- 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.

In this leaflet:

1. What Pholcodine Linctus is and what it is used for
2. Before you take Pholcodine Linctus
3. How to take Pholcodine Linctus
4. Possible side effects
5. How to store Pholcodine Linctus
6. Further 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. 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 your child plenty of warm clear fluids to drink.

3. To help 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

Children under 6 years should not be given this medicine.

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

- asthma
- kidney problems
- a persistent cough
- a cough with excessive secretions
- a problem with drug abuse (now or in the past)
- are pregnant or breast-feeding.

Take care if giving Pholcodine Linctus to the elderly or to children.

Supervision of these patients is advisable.

Taking other medicines

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:

- 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 (drug used 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 during pregnancy, 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.

Important information about some of the ingredients of Pholcodine Linctus

Pholcodine Linctus contains:

- **Sunset yellow (E110)** may cause allergic reactions
- **Sorbitol solution (E420)** if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 daily. |
| Children aged 6-12 years: | 5 ml up to 4 times daily. 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 | |

Do not exceed the stated dose.

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, Pholcodine Linctus 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 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.

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 store above 25°C, store in the original container. 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.

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. Further 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.

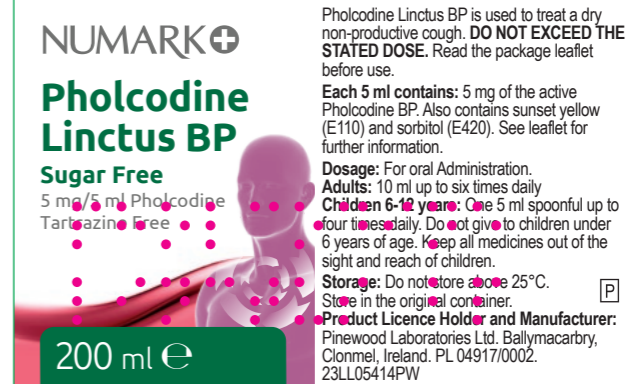
What Pholcodine Linctus looks like and contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Limited, Ballymacarbray, Clonmel, Co. Tipperary, Ireland. PL 04917/0002. Text Revised July 2019.

Produced for: Numark, Amber Close, Tamworth, Staffs, B77 4RP, UK.



Pholcodine Linctus BP is used to treat a dry non-productive cough. **DO NOT EXCEED THE STATED DOSE.** Read the package leaflet before use.

Each 5 ml contains: 5 mg of the active Pholcodine BP. Also contains sunset yellow (E110) and sorbitol (E420). See leaflet for further information.

Dosage: For oral Administration.
Adults: 10 ml up to six times daily
Children 6-12 years: One 5 ml spoonful up to four times daily. Do not give to children under 6 years of age. Keep all medicines out of the sight and reach of children.

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

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LINCTUS BP