

Galenphol Strong Linctus

(Pholcodine monohydrate)

Important information about Galenphol Strong Linctus
• This medicine relieves the symptoms of dry coughs in adults, the elderly and children over 12 years.

Do not take....

- If you have breathing problems including bronchitis. See section 2.
- Or give to children under 12 years.
 Avoid drinking alcohol while taking this medicine.
- · With other cough and cold medicines.

Now read the rest of the leaflet before you use this medicine. It includes other information which might be especially important for you.

- Keep this leaflet. You may need to read it again.
 Ask your pharmacist if you need any more information or advice.
- · If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. What the medicine is for

Galenphol Strong Linctus contains pholcodine monohydrate which reduces the desire to cough. It is used to relieve dry coughs which are without phlegm.

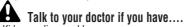
2. Before you use this medicine

have...

Do not use the medicine if you

- An allergy to any of the ingredients listed in section 6.
- Liver disease
- Shallow breath or breathing difficulties.
- An asthma attack.
- Taken MAOIs (monoamine oxidase inhibitors) for depression within the last two weeks.

· Ever developed a severe skin rash or skin that peels, blisters and/or sores in the mouth after taking this medicine or other pholcodine-containing medicines. Or you are under 12 years old.



- Kidney or liver problems.A history of asthma or other breathing problems including bronchitis.
- A cough for a long time or a cough which produces lots of phlegm.
- A history of drug abuse; pholoodine is an opioid and addiction is observed with opioids as a class.

Serious skin reactions, including acute generalized exanthematous pustulosis (AGEP), have been reported with the use of this medicine. 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.

Talk to your doctor or pharmacist if you are taking.... Medicine for high blood pressure, e.g. ACE inhibitors,

- beta blockers.
- Diuretics, which help remove fluid from the body, e.g. furosemide, hydrochlorothiazide.
- Medicines used to treat sleeplessness, anxiety and schizophrenia.
- Alcohol or tranquillisers.
- Pain killers, e.g. morphine.
- Or are having surgery, as muscle relaxants used may react with this medicine.

Concomitant use of this product and sedative medicines such as benzodiazepines or related drugs increases the

risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe this product together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Pregnant or breastfeeding....
Ask your doctor or pharmacist for advice before using this medicine if you are pregnant, might be pregnant or are breastfeeding. Galenphol Strong Linctus should not be used in pregnancy unless the doctor has told you to

If you use it when breastfeeding, pholcodine monohydrate in this medicine will be present in small amounts in your milk.

Driving and using machines.... This medicine may cause drowsiness. If you are affected do not drive or operate machinery.

Important information about some of the ingredients

This medicine contains:

- 77mg of alcohol (ethanol) in each 5ml dose. The amount in 5ml of this medicine is equivalent to less than 2ml of beer or 1ml of wine. The small amount of alcohol in this medicine will not have any noticeable
- · sodium parahydroxybenzoates, amaranth dye and sunset yellow dye which may cause allergic reactions (possibly delayed). Turn over 🖈

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• less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

3. How to use this medicine

Take this medicine by mouth.

The normal dose is given below but your doctor may prescribe a different amount for you.

Always follow the instructions given by the doctor or pharmacist.

Adults and children over 12 years

 Take one 5ml spoonful every four to six hours. Warning: Do not take more medicine than the label tells you to.

Children under 12 years
Do not give to children under 12 unless your doctor tells you to.

If your symptoms persist you should ask your doctor for advice.



If you take too much

If you accidentally take too much, see a doctor straight away. Take the pack with you to show which medicine you have swallowed.

4. Possible side effects

Like all medicines Galenphol Strong Linctus can have side effects, although these don't affect everyone.

Important side effects:

If you think you have any of the following side effects or symptoms, stop using this medicine and contact or see a doctor immediately.

• Allergic reactions which cause difficulty in breathing,

- fever, swelling of the mouth, lips or skin, severe rashes and itching.
- 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).

Other possible side effects are:

- Feeling sick.
- Constipation.
- Dizziness.
- Drowsiness
- Getting excited.
- Confusion.
- Being sick.
- Rash

 Failure to cough up phlegm.
If you notice these or any other side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.

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. Storing this medicine

- · Keep this medicine out of the sight and reach of children.
- Protect from light.
- Do not store above 25°C.
- Do not use after the expiry date shown on the pharmacist's label.
- Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of any unused medicine. These measures will help to protect the environment.

6. Further information

What is in this medicine The active ingredient per 5ml is: pholcodine monohydrate 10mg.

The other ingredients are:

citric acid monohydrate(E330), sodium methyl parahydroxybenzoate (E219), sodium ethyl parahydroxybenzoate (E215) and sodium propyl parahydroxybenzoate, glycerol (E422), ethanol, sunset yellow dye (E110), amaranth dye (E123), saccharin sodium, carmellose sodium, menthol, condensed milk flavour, aniseed flavour and purified water.

What the medicine looks like

Galenphol Strong Linctus is a thick orange-red liquid which smells of menthol and aniseed. It is dispensed for you by the pharmacist.

Marketing authorisation holder and manufacturer Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK.

This leaflet was last revised in November 2021

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