

PACKAGE INFORMATION LEAFLET CODEINE LINCTUS BP Codeine Phosphate 15 mg/5 ml

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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.

- 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 your doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

WHAT CODEINE LINCTUS IS AND WHAT IT IS USED FOR

Codeine Linctus is a medicine which helps you to stop coughing, especially if you have a non-productive cough. It is related to morphine and acts to stop your automatic cough response.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE CODEINE LINCTUS

- Do not take Codeine Linctus if you:

 are allergic (hypersensitive) to Codeine or any of the other ingredients listed (see Section 6 and end of Section 2)
- have liver disease
- have breathing problems (i.e. ventilatory failure)
- know that you metabolise very rapidly codeine into morphine are breast-feeding
- are under 12 years old.

Adolescents older than 12 years of age

Codeine is not recommended in adolescents with compromised respiratory function for the treatment of cough

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

- liver or kidney problems
- an under active thyroid (i.e. hypothyroidism)
- a problem of drug abuse (now or in the past)
- pregnant or breast-feeding

Take care if giving Codeine Linctus to the elderly. Supervision of these patients is advisable.

Warnings and precautions

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not have an effect on their cough symptoms. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Other medicines and Codeine Linctus

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

- anti-depressants known as monoamine-oxidase inhibitors (MAOIs)
- CNS depressants (e.g. chlorpromazine)
- anticholinergics (e.g. oxybutynin) hydroxyzine
- methadone
- levallorphan
- neuromuscular blocking agents (e.g. atracurium)
- metoclopramide
- mexiletine
- hypnotics (such as sleeping tablets) and sedatives

Codeine Linctus with food, drink and alcohol

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

Ask your doctor for advice before taking any medicine during pregnancy. Do not take codeine while you are breast-feeding. Codeine and morphine passes into

Driving and using machines

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

- The medicine can affect your ability to drive as it may make you sleepy or dizzy.

 Do not drive while taking this medicine until you know how it affects you.

 It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence 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 or in the information provided with the medicine and
- o It was not affecting your ability to drive safely

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Important information about some of the ingredients of Codeine Linctus

Codeine Linctus also contains

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

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- Sunset yellow (E110): which may cause allergic reactions
- Ethanol: This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

HOW TO TAKE CODEINE LINCTUS

Always take the product exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Only to be taken by mouth.

The recommended dose is:

Adults:	One to two 5 ml spoonfuls 3 – 4 times daily
Elderly or weak patients:	Dosage should be reduced
Adolescents (12 to 18 years):	One to two 5 ml spoonfuls, 3 – 4 times daily
Children (under 12 years):	Not for use in children under the age of 12 years

Do not exceed the stated dose

If you take more Codeine Linctus than you should

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

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.

POSSIBLE SIDE EFFECTS

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

STOP using Codeine 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.

Side effects which may occur include:

- nausea, vomiting, constipation
- loss of appetite
- flushing of face
- slow or shallow breathing
- difficulty coughing up mucous or saliva (particularly in patients with chronic bronchitis and bronchiectasis)

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. By reporting side effects you can help provide more information on the safety of this medicine.

HOW TO STORE CODEINE LINCTUS

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Keep in the original container in order to protect from light. Do not use this product after the expiry date which is stated on the bottle.

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.

CONTENTS OF THE PACK AND OTHER INFORMATION

What Codeine Linctus contains

- The active ingredient is: Codeine Phosphate, 15 mg in each 5 ml
- The other ingredients are: sodium benzoate (E211), citric acid monohydrate, saccharin sodium (E954), sunset yellow (E110), sorbitol solution (E420), orange flavour, carboxymethylcellulose, propylene glycol and purified water (see end of Section 2 for further information)

What Codeine Linctus looks like and contents of the pack

Codeine Linctus is a clear orange syrup, with an orange flavour, available in 2000 ml and 1000 ml plastic bottles or in 100 ml, 125 ml and 200 ml amber glass bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland. PL 04917/0001

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