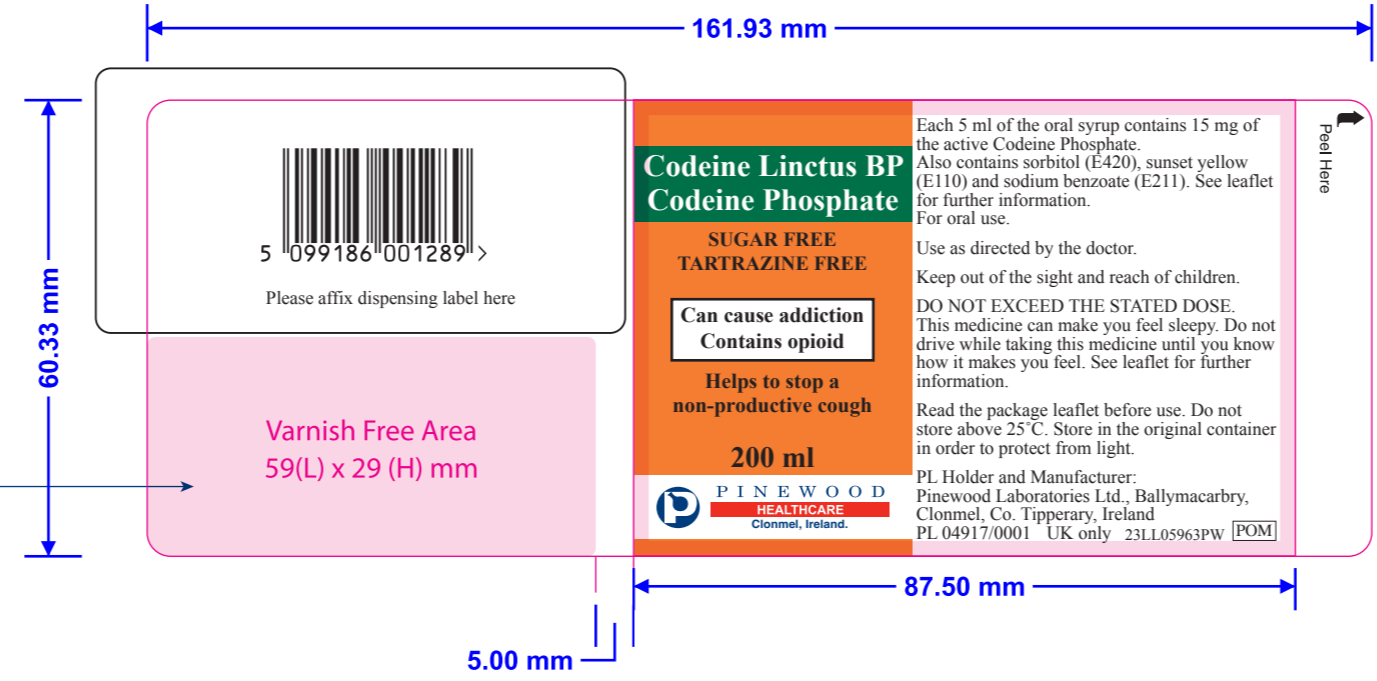




Artwork Code:	23LL05963PW	Font:	Times New Roman 11pt - 7pt
Date:	08/04/24	Dimensions:	162 x 60 mm (6 page FAF)
Printing:	Black 1655	3425	281 485
Non-Printing:	Keyline	Text Free Area	Braille
Version:			3

Other information: Previous artwork code - 23LL05493PW  
 Reclassification from P to POM  
 Addition of dispensing label area  
 Dimensions changed from 124x52mm 6pg to 162x60mm 6pg  
 Font size changed from 7.5pt to 7pt  
 Overprint area increased for serialisation



**Overprinting Area for 2D Code and Human Readable Text**  
 Area to be unvarnished & free from any print. The following will be included in the 2D Code and Human Readable Text:  
 PC  
 SN  
 BN  
 EXP  
 (variable info will be printed online when available)

**Codeine Linctus BP**  
**Codeine Phosphate**

SUGAR FREE  
 TARTRAZINE FREE

Can cause addiction  
 Contains opioid

Helps to stop a non-productive cough

200 ml

PINEWOOD HEALTHCARE  
 Clonmel, Ireland.

Each 5 ml of the oral syrup contains 15 mg of the active Codeine Phosphate. Also contains sorbitol (E420), sunset yellow (E110) and sodium benzoate (E211). See leaflet for further information. For oral use.

Use as directed by the doctor.  
 Keep out of the sight and reach of children.  
**DO NOT EXCEED THE STATED DOSE.**  
 This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See leaflet for further information.

Read the package leaflet before use. Do not store above 25°C. Store in the original container in order to protect from light.

PL Holder and Manufacturer:  
 Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland  
 PL 04917/0001 UK only 23LL05963PW [POM]

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<p>87.50 mm</p> <p><b>PACKAGE INFORMATION LEAFLET</b>  <b>CODEINE LINCTUS BP</b>  <b>Codeine Phosphate 15 mg/5 ml</b></p> <p>This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.</p> <p>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</p> <p>Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.</p> <ul style="list-style-type: none"> <li>- Keep this leaflet. You may need to read it again</li> <li>- Ask your pharmacist if you need more information or advice</li> <li>- This medicine has been prescribed for you only. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours</li> <li>- 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.</li> <li>- You must talk to your doctor if you do not feel better or if you feel worse.</li> </ul> <p><b>What is in this leaflet:</b></p> <ol style="list-style-type: none"> <li>1. What Codeine Linctus is and what it is used for</li> <li>2. What you need to know before you take Codeine Linctus</li> <li>3. How to take Codeine Linctus</li> <li>4. Possible side effects</li> <li>5. How to store Codeine Linctus</li> </ol>	<p>6. Contents of the pack and other information</p> <p><b>1. WHAT CODEINE LINCTUS IS AND WHAT IT IS USED FOR</b>    This medicine has been prescribed for you to help you stop coughing, especially if you have a non-productive cough.</p> <p>It contains the active codeine which belongs to a class of medicines called opioids. This medicine has been prescribed to you and should not be given to anyone else.</p> <p>Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.</p> <p><b>2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CODEINE LINCTUS</b></p> <p><b>Do not take Codeine Linctus if you:</b></p> <ul style="list-style-type: none"> <li>• are allergic (hypersensitive) to Codeine or any of the other ingredients listed (see Section 6 and end of Section 2)</li> <li>• have liver disease</li> <li>• have breathing problems (i.e. ventilatory failure)</li> <li>• know that you metabolise very rapidly codeine into morphine</li> <li>• are breast-feeding</li> <li>• are under 12 years old.</li> </ul> <p><b>Adolescents older than 12 years of age</b>    Codeine is not recommended in adolescents with compromised respiratory</p>	<p>function for the treatment of cough.</p> <p><b>Warnings and precautions</b>    Talk to your prescriber before taking this medicine if you:</p> <ul style="list-style-type: none"> <li>• are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.</li> <li>• have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.</li> <li>• feel you need to take more of Codeine Linctus to get the same level of relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medicine.</li> </ul> <p>Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.</p> <p>Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.</p> <p>Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine</p>	<p>suddenly as you will be more likely to experience withdrawal symptoms.</p> <p>Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.</p> <p><b>Take special care with Codeine Linctus or talk to your doctor or pharmacist if you have:</b></p> <ul style="list-style-type: none"> <li>• asthma</li> <li>• liver or kidney problems</li> <li>• an under active thyroid (i.e. hypothyroidism)</li> <li>• a problem of drug abuse (now or in the past) or are</li> <li>• pregnant or breast-feeding</li> </ul> <p>Take care if giving Codeine Linctus to the elderly. Supervision of these patients is advisable.</p> <p>Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine.</p> <p>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</p>	<p>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.</p> <p><b>Other medicines and Codeine Linctus</b>    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:</p> <ul style="list-style-type: none"> <li>• anti-depressants known as monoamine-oxidase inhibitors (MAOIs)</li> <li>• CNS depressants (e.g. chlorpromazine)</li> <li>• anticholinergics (e.g. oxybutynin)</li> <li>• hydroxyzine</li> <li>• methadone</li> <li>• levallorphan</li> <li>• neuromuscular blocking agents (e.g. atracurium)</li> <li>• metoclopramide</li> <li>• mexiletine</li> <li>• hypnotics (such as sleeping tablets) and sedatives</li> </ul> <p><b>Codeine Linctus with food, drink and alcohol</b>    You must not drink alcohol while taking this medicine as this may increase drowsiness.</p>	<p><b>Pregnancy and breast-feeding</b>    If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Do not take Codeine Linctus if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. If you use Codeine Linctus during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.</p> <p>Do not take Codeine Linctus while you are breast-feeding as codeine passes into breast milk and will affect your baby.</p> <p><b>Driving and using machines</b>    Codeine may cause drowsiness. Do not drive or operate machinery until you know how the medicine will affect you.</p> <p>The medicine can affect your ability to drive as it may make you sleepy or dizzy.</p> <ul style="list-style-type: none"> <li>• Do not drive while taking this medicine until you know how it affects you.</li> <li>• It is an offence to drive if this medicine affects your ability to drive.</li> <li>• However, you would not be committing an offence if:       <ul style="list-style-type: none"> <li>o The medicine has been prescribed to treat a medical or dental problem and</li> </ul> </li> </ul>
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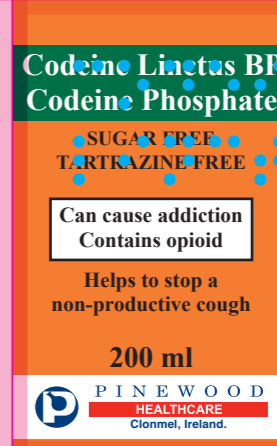
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<p>o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and</p> <p>o It was not affecting your ability to drive safely</p> <p>Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.</p> <p><b>Important information about some of the ingredients of Codeine Linctus</b>    Codeine Linctus also contains:</p> <ul style="list-style-type: none"> <li>• <b>Sorbitol solution (E420):</b> If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product</li> <li>• <b>Sunset yellow (E110):</b> which may cause allergic reactions</li> <li>• <b>Ethanol:</b> This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.</li> </ul> <p><b>3. HOW TO TAKE CODEINE LINCTUS</b>    Your prescriber should have discussed with you, how long the course of treatment will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Always take the product exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.</p> <p>Only to be taken by mouth.</p>	<p>The recommended dose is:</p> <table border="1"> <tr> <td><b>Adults</b></td> <td>One to two 5 ml spoonfuls 3 – 4 times daily</td> </tr> <tr> <td><b>Elderly or weak patients</b></td> <td>Dosage should be reduced</td> </tr> <tr> <td><b>Adolescents (12 to 18 years)</b></td> <td>One to two 5 ml spoonfuls 3 – 4 times daily</td> </tr> <tr> <td><b>Children (under 12 years)</b></td> <td>Not for use in children under the age of 12 years</td> </tr> </table> <p>Do not exceed the stated dose.</p> <p><b>If you take more Codeine Linctus than you should</b>    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.</p> <p><b>If you forget to take Codeine Linctus</b>    If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced times. <b>Do not</b> take a double dose to make up for the forgotten dose.</p> <p><b>If you stop taking Codeine Linctus</b>    Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat</p>	<b>Adults</b>	One to two 5 ml spoonfuls 3 – 4 times daily	<b>Elderly or weak patients</b>	Dosage should be reduced	<b>Adolescents (12 to 18 years)</b>	One to two 5 ml spoonfuls 3 – 4 times daily	<b>Children (under 12 years)</b>	Not for use in children under the age of 12 years	<p>(palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.</p> <p>If you have any further questions on the use of this product, ask your doctor or pharmacist.</p> <p><b>4. POSSIBLE SIDE EFFECTS</b>    Like all medicines, Codeine Linctus can cause side effects, although not everybody gets them.</p> <p><b>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.</b></p> <p>Side effects which may occur include:</p> <ul style="list-style-type: none"> <li>• nausea, vomiting, constipation</li> <li>• loss of appetite</li> <li>• flushing of face</li> <li>• slow or shallow breathing</li> <li>• difficulty coughing up mucus or saliva (particularly in patients with chronic bronchitis and bronchiectasis)</li> <li>• dependence and addiction (frequency unknown) (see section "How do I know if I am addicted?")</li> </ul>	<p><b>Drug Withdrawal</b>    When you stop taking Codeine Linctus, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.</p> <p><b>How do I know if I am addicted?</b>    If you notice any of the following signs whilst taking Codeine Linctus, it could be a sign that you have become addicted.</p> <ul style="list-style-type: none"> <li>- You need to take the medicine for longer than advised by your prescriber</li> <li>- You feel you need to use more than the recommended dose</li> <li>- You are using the medicine for reasons other than prescribed</li> <li>- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again</li> </ul> <p>If you notice any of these signs, it is important you talk to your prescriber.</p> <p><b>Reporting of side effects</b>    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 <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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.</p> <p><b>5. HOW TO STORE CODEINE LINCTUS</b>    Keep this medicine out of the sight and reach of children. Do not store above</p>	<p>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.</p> <p><b>6. CONTENTS OF THE PACK AND OTHER INFORMATION</b>  <b>What Codeine Linctus contains</b></p> <ul style="list-style-type: none"> <li>- The active ingredient is: Codeine Phosphate, 15 mg in each 5 ml</li> <li>- 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)</li> </ul> <p><b>What Codeine Linctus looks like and contents of the pack</b>    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.</p> <p><b>Marketing Authorisation Holder and Manufacturer</b>    Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland. PL 04917/0001</p> <p>This leaflet was last updated in 03/2024</p>	 <p>Each 5 ml of the oral syrup contains 15 mg of the active Codeine Phosphate. Also contains sorbitol (E420), sunset yellow (E110) and sodium benzoate (E211). See leaflet for further information.</p> <p>Use as directed by the doctor.    Keep out of the sight and reach of children.</p> <p><b>DO NOT EXCEED THE STATED DOSE.</b>    This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See leaflet for further information.</p> <p>Read the package leaflet before use. Do not store above 25°C. Store in the original container in order to protect from light.</p> <p>PL Holder and Manufacturer:    Pinewood Laboratories Ltd., Ballymacarbray, Clonmel, Co. Tipperary, Ireland    PL 04917/0001 UK only 23LL05963PW [POM]</p>
<b>Adults</b>	One to two 5 ml spoonfuls 3 – 4 times daily												
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Braille Translation:

**CODEINE LINCTUS BP**

