

and the benefits of treatment are considered to outweigh the potential harm to the baby.
If you use Pulmo Bailly during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Do not take Pulmo Bailly while you are breastfeeding as Codeine and guaiaicol passes into breast milk and will affect your baby.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pulmo Bailly can cause side effects, although not everybody gets them.
All medicines can cause allergic reactions, although serious allergic reactions are very rare. **Speak to your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).** Pulmo Bailly may cause **drowsiness or constipation.**

Medicines containing codeine may cause the following side effects:

- feeling sick (nausea)
- vomiting
- abdominal pains
- feeling 'high' (euphoria)
- seeing or hearing things that aren't there (hallucinations)
- dizziness on standing
- little or no urine production
- fainting
- sedation
- visual disturbances
- rapid, slow, or irregular heartbeat

Unknown frequency: dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Pulmo Bailly, 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Pulmo Bailly, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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.

5. HOW TO STORE PULMO BAILLY

Keep this medicine out of the sight and reach of children. Do not store above 25 °C and protect from light. Do not use Pulmo Bailly after the expiry date as indicated on the label and box. The expiry date refers to the last day of the month.
Do not throw away any medicines via waste-water or with household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pulmo Bailly contains

The active substances are Codeine 7.0 mg per 5 ml and Guaiaicol 75.0 mg per 5 ml
The other ingredients are: phosphoric acid, sucrose, chloroform, glycerol, burnt sugar solution and purified water.

What Pulmo Bailly looks like and contents of the pack

Pulmo Bailly is available as an amber glass bottle with plastic child resistant lid. Pack size: 90 ml.

Marketing Authorisation Holder

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PACKAGE LEAFLET: INFORMATION FOR THE USER

This medicine contains the active ingredient codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What Pulmo Bailly is and what it is used for
2. What you need to know before you take Pulmo Bailly
3. How you take Pulmo Bailly
4. Possible side effects
5. How to store Pulmo Bailly
6. Contents of the pack and other information

1. WHAT PULMO BAILLY IS AND WHAT IT IS USED FOR

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

Pulmo Bailly is a pale amber oral liquid that contains the active ingredients codeine and guaiaicol.

Pulmo Bailly is prescribed for you to help prevent coughing and loosens phlegm. It contains Codeine which belongs to a class of medicines called opioids.

Codeine is one of a group of medicines called anti-tussives (help to prevent coughing) and guaiaicol is an expectorant (loosens phlegm).

This medicine has been prescribed to you and should not be given to anyone else.



Pulmo Bailly is for the relief of coughs caused by:

- colds
- bronchial (lung) catarrh
- flu
- upper airways infections such as laryngitis (inflammation of the voice box causing hoarseness) and pharyngitis (sore throat)

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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PULMO BAILLY**Do not take Pulmo Bailly:**

- If you are **allergic** (hypersensitive) to **codeine, guaiacol** or **any other ingredients of Pulmo Bailly** (see list of ingredients in Section 6).
- If you are **pregnant** or **breastfeeding**
- If you have a **severe liver disease**
- If you have a **severe breathing problem** or **asthma**
- If you have a **head injury** or you have been told you have **high pressure in your skull** (intracranial pressure)
- If you have a **disease or problem with your digestive tract**
- If you know that you metabolise very rapidly codeine into morphine

Warnings and precautions**Talk to your doctor or pharmacist before taking Pulmo Bailly:**

- If you have breathing problems
- If you have a kidney disorder
- If you have a liver disorder
- If you have inflammation of the large intestine (ulcerative colitis)
- If you have an enlarged prostate gland
- If you have chronic bronchitis (long-lasting inflammation of the airways)
- If you have bronchiectasis (abnormal widening of one or more airways) as the product may cause build-up of phlegm in the lungs.

Prolonged use in the elderly may cause severe constipation.

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such

as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

- feel you need to take more of Pulmo Bailly 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 cough reliever.

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.

Rarely, increasing the dose of this medicine can make you more sensitive to Cough. If this happens, you need to speak to your prescriber about your treatment.

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 suddenly as you will be more likely to experience withdrawal symptoms. 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.

Other medicines and Pulmo Bailly

You should tell your doctor if you are taking or have taken any medicines, including medicines obtained without a prescription. This is especially important of the following medicines as they may interact with Pulmo Bailly:

- Alcohol
- Drugs that affect the brain such as sleeping tablets
- Metoclopramide (used for digestive disorders or to prevent sickness)

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant or breast-feeding. Codeine and morphine passes into breast milk.

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.

Driving and using machines

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how it affects you. It may be

an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>

Important information about some of the ingredients of Pulmo Bailly

Pulmo Bailly contains sucrose and burnt sugar solution. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pulmo Bailly.

3. HOW YOU TAKE PULMO BAILLY

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

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. If you stop taking “Pulmo Bailly”

The recommended doses are:

Dosage (Adults): Up to two 5 ml teaspoonfuls should be taken in half a small glass of water three times daily before meals. A further two teaspoonfuls should be taken at bedtime to help sleep. Sugar or fruit squash may be added.

Dosage (Elderly): The elderly may need a reduced dose if they have a liver or kidney disorder.

Pulmo Bailly is not recommended to children under 18 years old.

If you take more Pulmo Bailly than you should.

Contact your doctor or go to your nearest hospital immediately. Symptoms of overdose include sleepiness, rash, pinpoint pupils, vomiting, itching, coordination problems, excitement, nettle rash, and shallow breathing. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Pulmo Bailly

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 (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Pregnancy

Do not take Pulmo Bailly if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber