



PATIENT INFORMATION LEAFLET
Codinex™
Codeine Phosphate 15 mg/5 ml Oral Solution

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Codinex is and what it is used for
2. Before you take Codinex
3. How to take Codinex
4. Possible side effects
5. How to store Codinex
6. Further information

1. WHAT CODINEX IS AND WHAT IT IS USED FOR

Codinex contains codeine and is used to treat a dry or painful cough.

2. BEFORE YOU TAKE CODINEX

Do NOT take Codinex if you:

- have an allergy (hypersensitivity) to codeine phosphate or any of the other ingredients of Codinex (see Section 6 and end of Section 2).
- have liver disease
- have breathing problems e.g. bronchitis or other respiratory problems
- are pregnant or breast-feeding
- If you are under 12 years old.
- If you know that you metabolise very rapidly codeine into morphine.
- If you are breastfeeding.

Adolescents older than 12 years of age

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

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 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.

Take special care

This product contains Codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms such as restlessness and irritability, once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

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 particularly the following:

- central nervous system depressants e.g. chlorpromazine or diazepam
- hydroxyzine (an antihistamine)
- antipsychotic drugs for schizophrenia, bipolar disorder or mania
- anticholinergic medicines e.g. atropine
- metoclopramide to treat nausea and vomiting
- drugs to help you sleep such as barbiturates or the herbal drug valerian
- drugs for anxiety such as benzodiazepines
- anti-depressants known as monoamine-oxidase inhibitors (MAOIs) or 'tricyclics'
- methadone.

Taking Codinex with food and drink

Do not drink alcohol whilst taking this medicine as it may increase the risk of drowsiness.

Pregnancy and breast-feeding

Do not take Codinex while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

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

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Important information about some of the ingredients of Codinex

Codinex contains:

- **Sunset yellow (E110):** which may cause allergic reactions
- **Sorbitol (E420):** if you have been told that you have an intolerance to some sugars, contact your doctor before taking this product.
- **Ethanol:** This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

3. HOW TO TAKE CODINEX

Always take this medicine exactly as the doctor or pharmacist has told you; you should check with him/her if you are not sure.

To be taken by mouth only. Do not exceed the stated dose.

Codinex is normally used for short-term relief of symptoms, take this medicine for as long as your doctor tells you to.

Adults: one to one and a half 5 ml spoonfuls (5 ml to 7.5 ml), three to four times a day.

Elderly / debilitated patients: the dose should be reduced. Your doctor will advise you.

Adolescents (12 to 18 years): one to one and a half 5 ml spoonfuls (5 ml to 7.5 ml), three to four times a day.

Children (under 12 years): not for use in children under the age of 12 years.

If you take more Codinex than you should

If you, or someone else, have taken too much medicine, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you.

If you forget to take Codinex

If you miss a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining dose at the correct time. Do not take a double dose to make up for a 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, Codinex can cause side effects, although not everybody gets them.

STOP taking Codinex and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Other side effects:

- Constipation, loss of appetite or flushing of face may occur occasionally
- slow or shallow breathing
- inability to clear the secretion (sputum) in your respiratory tract particularly if you have bronchitis.

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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel:

+353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can

help provide more information on the safety of this medicine.

5. HOW TO STORE CODINEX

Keep out of the sight and reach of children.

Do not use Codinex after the expiry date which is stated on the bottle or carton after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original container.

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 Codinex contains

- The **active** ingredient is codeine phosphate. Each 5 ml of Codinex contains a 15 mg dose of codeine phosphate (equivalent to 11.8 mg of codeine).
- The **other** ingredients are: sodium benzoate (E211), citric acid monohydrate, saccharin sodium (E954), sunset yellow (E110), sorbitol, sodium carmellose, propylene glycol, orange flavour and purified water (see end of Section 2 for further information about the ingredients).

What Codinex looks like and contents of the pack

Codinex is a clear, dark yellow, orange flavoured oral solution available in 100 ml, 150 ml, 200 ml or 500 ml amber glass bottles with child-resistant closures or 1 litre or 2 litre plastic bottles with tamper evident screw caps.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., trading as Pinewood Healthcare, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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