

Package leaflet: Information for the user
Codinex™
Codeine Phosphate 15 mg/5 ml Oral Solution

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass this medicine 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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

1. What Codinex is and what it is used for

Codinex contains codeine phosphate. It is used to relieve dry coughs (coughs without phlegm) in adults.

2. What you need to know before you take Codinex

Do NOT take Codinex

- if you are allergic to codeine phosphate or any of the other ingredients of this medicine (listed in section 6)
- if you have liver disease
- if you have breathing problems e.g. bronchitis or other respiratory problems
- if you are under 12 years old
- if you know that you metabolise very rapidly codeine into morphine
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Codinex.

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
- 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

- Do not give Codinex to children under 12 years of age
- Codinex is not recommended for use in adolescents aged between 12 and 18 years of age with breathing problems because the symptoms of morphine toxicity may be worse in this age group.

Other medicines and Codinex

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Concomitant use of Codinex 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 Codinex 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.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist if you are not sure.

Pregnancy

Codinex is not recommended if you are pregnant. It should only be taken during pregnancy if your doctor considers it essential. You must consult your doctor.

Breast-feeding

Do not take Codinex while you are breast-feeding, see section 'Do NOT take Codinex' above. Codeine and morphine pass 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.

Codinex contains sunset yellow, sorbitol and ethanol

- **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. Check with your doctor or pharmacist if you are not sure.

Codinex is used for the relief of the symptoms of a dry cough (without phlegm).

The recommended dose is:

Adults:

- One to one and a half 5 ml measures (5 ml to 7.5 ml), up to three to four times a day only if required.
- You can repeat the dose every 4 to 6 hours if required, but do not take more than 30 mls of Codinex in 24 hours.
- **Do not take for more than 3 days** without medical supervision.

Elderly / debilitated patients: The recommended dose should be reduced. You will need to get advice from your doctor.

Adolescents (12 to 18 years): As for the adult dose above. Codinex is not recommended for use in adolescents between the ages of 12 and 18 with breathing problems.

Children (under 12 years): Do not give to children under the age of 12 years.

Other information:

- For oral use only.
- Do not exceed the stated dose or frequency.
- Do not take for more than 3 days without medical supervision.

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Codinex

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not throw away any medicines via wastewater or 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 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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