

Package Leaflet: Information for the patient

Codeine phosphate hemihydrate 10 mg tablets
Codeine phosphate hemihydrate 15 mg tablets
Codeine phosphate hemihydrate 20 mg tablets
Codeine phosphate hemihydrate 30 mg tablets

codeine phosphate hemihydrate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Codeine phosphate hemihydrate tablets (hereinafter: Codeine phosphate hemihydrate) is and what it is used for
2. What you need to know before you take Codeine phosphate hemihydrate
3. How to take Codeine phosphate hemihydrate
4. Possible side effects
5. How to store Codeine phosphate hemihydrate
6. Contents of the pack and other information

1. What Codeine phosphate hemihydrate is and what it is used for

Codeine phosphate hemihydrate can be used in adults and children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

Codeine phosphate hemihydrate can also be used in adults and children over 12 years of age for symptomatic relief of dry cough.

Codeine phosphate hemihydrate tablets can also be used in adults for symptomatic relief of severe diarrhoea when treatment with loperamide failed.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

2. What you need to know before you take Codeine phosphate hemihydrate

Do not take Codeine phosphate hemihydrate

- If you are allergic to codeine or any of the other ingredients of this medicine (listed in section 6).
- If you have breathing problems, or other chronic lung disease
- If you have uncontrolled or partly controlled asthma
- If you suffer with alcoholism or liver failure
- If you are at a risk of blocked intestines
- If you have severe stomach cramps caused by a condition known as biliary colic
- If you are suffering from severe diarrhoea caused by certain medical conditions or poisoning
- If you have suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)

- If you are under 12 years old
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.
- If you are breast feeding
- If you know that you metabolise very rapidly codeine into morphine.
- If you are taking medicine called monoamine oxidase inhibitors (MAOIs) for depression or you have taken them within the previous 14 days.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Codeine phosphate hemihydrate:

- if you have a history of seizures or fits (epilepsy)
- if you suffer from a serious mental illness that affects your behaviour and actions (toxic psychosis)
- if you have suffered from alcoholism, drug abuse or dependence or mental illness
- if you have a heart disease, especially when your heart rhythm is abnormally fast (supraventricular tachycardia)
- if you suffer from asthma or breathing problems
- if you have inflammatory bowel disease including severe bloody diarrhoea (pseudomembranous colitis)
- if you recently had surgery on your gastro-intestinal tract or urinary system
- if you have kidney or liver problems;
- if you have difficulty in passing urine because of enlarged prostate gland or due to other reasons
- if you have diseased adrenal glands (Addison's disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma)
- if you suffer from muscle weakness (myasthenia gravis)
- if you have low blood pressure or an under-active thyroid gland
- if you are pregnant
- if you are older or frail
- if you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

The use of codeine may lead to constipation. If you are not taking codeine for the treatment of severe diarrhoea, you may also need a laxative.

Do not take for longer than directed by your prescriber. Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets. Taking a painkiller regularly for headaches too often or for too long can make them worse.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Codeine phosphate hemihydrate tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Codeine phosphate hemihydrate tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").

- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Codeine phosphate hemihydrate tablets it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain or cough.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, "If you stop taking Codeine phosphate hemihydrate").

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cough. 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 provide enough pain relief or relieve their cough. 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.

Sleep-related breathing disorders

Codeine phosphate hemihydrate tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Children and adolescents

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children and adolescents for severe diarrhoea

Codeine should not be used for severe diarrhoea in children and adolescents.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Adolescents older than 12 years of age

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

Other medicines and Codeine phosphate hemihydrate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially:

- monoamine oxidase (MAO) inhibitors (medicines used to treat depression or Parkinson's disease, such as moclobemide, linezolid, selegiline). Codeine phosphate hemihydrate tablets should not be taken with MAO inhibitors at the same time and during a 2-week period after stopping MAOI inhibitors (see section "Do not take Codeine phosphate hemihydrate")
- tricyclics (medicines used to treat depression, e.g. amitriptyline, clomipramine)
- ciprofloxacin (antibacterial medicine used to treat infections)
- metoclopramide or domperidone (used to prevent sickness)
- mexiletine or quinidine (used to treat irregular heartbeats)
- loperamide or kaolin (used to treat diarrhoea)
- cimetidine (used to treat stomach ulcers)
- medicines used to treat high blood pressure
- anti-HIV medicines (ritonavir)
- medicines used to treat allergies (antihistamines) that can cause drowsiness
- atropine (used to treat slow heart beats)
- medicines used to treat insomnia (hypnotics)
- medicines used to reduce irritation and excitement (sedatives) or anxiety (anxiolytics)
- medicines used to treat severe pain (narcotic analgesics)
- medicines used to treat pain during surgery (anaesthetics)
- medicines used to treat drug poisoning or drug dependence (buprenorphine, naltrexone, naloxone)
- sodium oxybate (used to treat narcolepsy)
- terbinafine (used to treat fungal infection)
- rifampicin (an antibiotic for tuberculosis)
- barbiturates (used to treat epilepsy)
- St. John's wort (a herbal medicine for depression)
- certain neuroleptics (used to treat schizophrenia)
- certain medicines used to treat depression
- gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

Concomitant use of Codeine phosphate hemihydrate tablets 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 Codeine phosphate hemihydrate tablets 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.

Codeine phosphate hemihydrate with food, drink and alcohol

DO NOT drink alcohol whilst taking Codeine phosphate hemihydrate tablets.

Pregnancy, breast-feeding and fertility

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. Codeine phosphate hemihydrate tablets should only be used during pregnancy if strictly needed.

Regular use during pregnancy may cause withdrawal symptoms in the newborn.

Do not take Codeine phosphate hemihydrate tablets while you are breastfeeding. Codeine and morphine passes into breast milk.

Always ask your doctor or pharmacist for advice before taking any other medicine.

Driving and using machines

These tablets may make you feel confused, cause fits, blurred vision or double vision or to see things that are not there. Codeine phosphate hemihydrate can affect your ability to drive as it may make you sleepy or dizzy. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine. If you feel that your reactions are affected, do not operate machinery.

Codeine phosphate hemihydrate contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Codeine phosphate hemihydrate tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Codeine phosphate hemihydrate

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Codeine phosphate hemihydrate when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, "If you stop taking Codeine phosphate hemihydrate").

Swallow the tablets with sufficient amount of water.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice. Codeine phosphate hemihydrate tablets should be used for the shortest duration necessary to relieve symptoms.

The usual dose is as follows:

Adults and children over 12 years:

For the relief of mild to moderate pain:

Children aged 12 years and above should take 30-60 mg every 6 hours, as needed. Do not take more than 240 mg codeine phosphate hemihydrate in 24 hours.

For cough: 15-30 mg three to four times a day.

Codeine is not recommended in adolescents over 12 years with compromised respiratory function for the treatment of cough.

Adults:

For the relief of severe diarrhoea: 15-60 mg three to four times daily up to a maximum of 240 mg daily.

Elderly patients with liver or kidney damage:

If you are elderly or you have liver or kidney damage your doctor may give you a smaller dose. It is particularly important to take this medicine exactly as directed by the doctor.

Do not exceed the stated dose.

Codeine should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

If you take more Codeine phosphate hemihydrate than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have

swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, confusion, fits, dizziness, nervousness, restlessness, excitement, hallucinations, muscle weakness, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate.

If you forget to take Codeine phosphate hemihydrate

If you discovered that you have not taken Codeine phosphate hemihydrate on time, when you are already to the next tablet, just follow the scheduled dose, as if nothing happened. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking Codeine phosphate hemihydrate

Do not stop taking these tablets without talking to your doctor. Treatment should continue for as long as your doctor feels it is needed. If you stop taking the tablets you may develop the following withdrawal symptoms: tremor, sleeping difficulty, feeling or being sick, sweating and increased heart rate, breathing or blood pressure, restlessness, irritability, anxiety, depression, anorexia, diarrhoea, excessive tears, runny nose, sneezing, yawning, hair standing on ends, widening of the pupil, weakness, fever, muscle cramps, dehydration.

If you have any further questions on the use of this medicine ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare (affects maximum 1 in 1000 people)

- Allergic reactions – serious allergic reaction which causes swelling of the face, tongue and throat (anaphylactoid reaction)
- Gastrointestinal system – patients who suffer from the inflammation of the bowels (i.e. chronic ulcerative colitis) may experience loose stool or constipation for a very long duration

Not known (frequency cannot be estimated from the available data)

- Allergic reactions - Oedema, skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face, fluid retention (e.g. swollen ankles and feet)
- Gastrointestinal system - constipation, feeling or being sick, dry mouth, abdominal pain, anorexia, loss of appetite, loose stools
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.
- Liver-bile duct problems - biliary spasm
- Heart - slow or fast heart rate, palpitations, low blood pressure, low blood pressure on standing, fainting
- Urinary system - pain and difficulty in passing urine and less frequent need to do so
- Nervous system - drowsiness, malaise, tiredness, dizziness, fits, increased pressure in the skull (painful eyes, change in vision or headache behind the eye), headache, tolerance (medicine has less effect) or dependence (suffer from withdrawal symptoms e.g. tremor, sweating, increased heart rate, increased breathing rate, raised blood pressure and feeling or being sick if the medicine is stopped too quickly)
- Psychiatric effect - mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, nightmares, confusion, disorientation
- Eyes - blurred or double vision, extremely small pupils
- Others - muscle stiffness, decrease in sex drive, breathing difficulty, low body temperature.

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 HPRC 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 Codeine phosphate hemihydrate

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

Do not use this medicine after the expiry date which is stated on the carton and blister /or bottle label after EXP. The expiry date refers to the last day of that month.

HDPE container: use within 1 year after first opening.

Blister packs: Store below 25 °C. Keep the blister in the outer carton in order to protect from light.

HDPE containers: This medicine does not require any special temperature storage conditions. Keep the container tightly closed in order to protect from light.

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 protect the environment.

6. Contents of the pack and other information

What Codeine phosphate hemihydrate contains

- The active substance is codeine phosphate hemihydrate.

Codeine phosphate hemihydrate 10 mg tablets: each tablet contains 10 mg codeine phosphate hemihydrate equivalent to 7.37 mg codeine.

Codeine phosphate hemihydrate 15 mg tablets: each tablet contains 15 mg codeine phosphate hemihydrate equivalent to 11.05 mg codeine.

Codeine phosphate hemihydrate 20 mg tablets: each tablet contains 20 mg codeine phosphate hemihydrate equivalent to 14.73 mg codeine.

Codeine phosphate hemihydrate 30 mg tablets: each tablet contains 30 mg codeine phosphate hemihydrate equivalent to 22.10 mg codeine.

- The other ingredients are cellulose, microcrystalline; lactose monohydrate; cellulose powder; silica, colloidal anhydrous; sodium starch glycolate; magnesium stearate.

What Codeine phosphate hemihydrate looks like and contents of the pack

Codeine phosphate hemihydrate 10 mg tablets:

White or almost white, oblong, both side convex tablets of 10 mm length, engraved with '10' on one side and scored on the other side. The tablet can be divided into equal doses.

30, 60, 90 or 100 tablets in clear, transparent PVC/PVdC//Alu blisters in a carton box with leaflet.

50, 100 or 250 tablets in white, opaque HDPE container with PP cap with desiccant and safety ring, in a carton box with leaflet.

Codeine phosphate hemihydrate 15 mg tablets:

White or almost white, round, flat-faced, bevelled-edge tablets of 7.5 mm diameter, engraved with '15' on one side..

30, 60, 90 or 100 tablets in clear, transparent PVC/PVdC//Alu blisters in a carton box with leaflet.

50, 100 or 250 tablets in white, opaque HDPE container with PP cap with desiccant and safety ring, in a carton box with leaflet.

Codeine phosphate hemihydrate 20 mg tablets:

White or almost white, round, flat, bevelled-edge tablets of 8.5 mm diameter, engraved with '20' on one

side and scored on the other side. The tablet can be divided into equal doses.

20, 30, 60, 90 or 100 tablets in clear, transparent PVC/PVdC//Alu blisters in a carton box with leaflet.
50, 100 or 250 tablets in white, opaque HDPE container with PP cap with desiccant and safety ring, in a carton box with leaflet.

Codeine phosphate hemihydrate 30 mg tablets:

White or almost white, hexagonal, flat, bevelled-edge tablets of 9.5 mm diameter, engraved with '30' on one side and scored on the other side. The tablet can be divided into equal doses.

30, 60, 90 or 100 tablets in clear, transparent PVC/PVdC//Alu blisters in a carton box with leaflet.
50, 100 or 250 tablets in white, opaque HDPE container with PP cap with desiccant and safety ring, in a carton box with leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal is authorised in the Member States of the European Economic Area under the following names:

Hungary: Codinep

The Netherlands: Codeïnefosfaat Expharma

Denmark, Norway, Sweden: Kodein ExtractumPharma

Ireland: Codeine phosphate hemihydrate

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