

## **Package leaflet: Information for the user**

### **Codant 30mg 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 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 Codant is and what it is used for
2. What you need to know before you take Codant
3. How to take Codant
4. Possible side effects
5. How to store Codant
6. Contents of the pack and other information

#### **1. What Codant is and what it is used for**

Codant can be used in 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. This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can also be used for relief of non-productive (dry) cough in adults. 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 Codant**

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 for headaches too often or for too long can make them worse. Do not use Codant for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codant may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses).

#### **Do not take Codant**

- if you are allergic to codeine phosphate hemihydrate or any of the other ingredients of this medicine (listed in section 6)
- if you know that you are allergic to other opioids
- if your age is less than 12 years.
- if you have used a drug of Monoamine oxidase inhibitors (MAOIs) group eg. Moclobemide for treatment of depression in last two week.
- if you are breast-feeding
- if you know that you metabolise very rapidly codeine into morphine
- if you have just had a head injury, or suffer from increased pressure on the brain
- if you suffer from breathing problems, for example emphysema or during an asthma attack (both of which can cause shortness of breath)
- if you have a blockage in the intestine
- if you have severe liver problems
- if you suffer from alcoholism
- if you are at a risk of having a blocked intestine (paralytic ileus)
- if you have been advised previously not to use 'opioids' (used for pain relief).
- 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 have recently had an operation on your liver, gall bladder or bile duct (biliary tract)

Codant Tablets are not recommended for patients who are in a coma. Speak to your doctor if this applies to you before you take Codant Tablets

## **Warnings and Precautions:**

### *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 Codant 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 Codant 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 Codant, 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 dry 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 Codant).

### *Sleep-related breathing disorders*

Codant 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.

Talk to your doctor or pharmacist before taking Codant

- if you have breathing problems. Your doctor will decide what is causing the problem before deciding whether you can take this product or not
- if you are using or have used within the last two weeks a group of medicines known as Monoamine Oxidase Inhibitors (MAOIs), e.g. Moclobemide for treating depression
- if you have liver, kidney or thyroid problems
- if you suffer from gall bladder disease, gall stones or problems of the bile duct

- if you know that you suffer from galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
- if you suffer from inflammatory bowel disease or ulcerative colitis
- if you suffer from fits
- if you have a narrowing in your urinary passage blocking the flow of the urine
- if you have recently had surgery on your gastrointestinal (digestive) or urinary tract
- if you have a tumor of the adrenal glands (phaeochromocytoma)
- if you are male and have an enlarged prostate gland and have difficulty urinating
- if you have a disease of the adrenal glands called Addison's disease
- if you have low blood pressure or are in shock
- if you have serious muscle weakness (myasthenia gravis)
- if you are elderly, very weak and in poor health
- if you suffer from acute colitis (inflammation of the colon characterized by abdominal pain, loss of appetite, bloating, diarrhoea) or pseudomembranous colitis (infection of the colon characterized by bloody stools, fever, abdominal cramps).
- if you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Codant may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.

Talk to your doctor or pharmacist or nurse if you experience any of the following symptoms while taking Codant: • 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.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. 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. 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.

### **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 (sleep disruption due to respiratory pauses).

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.

Your doctor should check you regularly if you are to use this medicine for a long time.

Tell your doctor if any of these apply to you before you are given this medicine.

### **Other medicines and Codant**

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

Some medicines interact with each other and this can alter their effect:

- Monoamine oxidase inhibitors, also known as MAOIs (e.g. linezolid, moclobemide, selegiline) can interact with Codeine if MAOIs have been taken at the same time or have been taken within the last 2 weeks
- Medicines which affect the nervous system such as sleeping tablets, diazepam, hydroxyzine and medicines to treat mental illness
- Some medicines to treat allergies called antihistamines (e.g. chlorphenamine)

- A group of medicines called anticholinergics (e.g. atropine)
- A group of medicines called antipsychotics (e.g. chlorpromazine, haloperidol)
- Medicines used to stop you from feeling sick (nausea) or being sick (vomiting) (e.g. metoclopramide and domperidone)
- Medicines for treating diarrhoea (e.g. loperamide, kaolin)
- Anaesthetics and some other medicines used before an operation
- Tricyclic antidepressants (e.g. amitriptyline, imipramine) which are used to treat depression or anxiety problems
- A group of medicines called opioid antagonists to treat addiction and overdose (e.g. buprenorphine, naltrexone, naloxone)
- Quinidine (medicine used to regulate the heart)
- Medicines to lower blood pressure (e.g. enalapril, losartan, indapamide, nifedipine)
- Ciprofloxacin (to treat bacterial infections)
- Ritonavir (for HIV infection)
- Medicines to treat heart disease (e.g. mexiletine)
- Cimetidine (used to treat stomach ulcers and to reduce the amount of acid in the stomach).
- Concomitant use of codeine 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.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

However, if your doctor does prescribe codeine 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.

#### **Codant with food, drink and alcohol:**

Avoid alcohol whilst taking Codant Tablets.

#### **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 for advice before taking this medicine.

##### Pregnancy

Codant Tablets should not be used during pregnancy or during labour. If codeine is given to you during pregnancy and you become dependent on it, there is a risk that the new-born baby may also be dependent and suffer from symptoms of withdrawal following delivery. If codeine is given during labour there is a risk that your baby could have difficulty starting breathing.

##### Breast-feeding:

Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines:**

Codeine may make you feel sleepy and dizzy. Do not drive or use machines if you develop these symptoms. You should ask your doctor for advice on driving and using machines.

#### **Tolerance and dependence:**

Codant Tablets can become less effective with repeated use. This is called tolerance and it means that the dose may need to be increased for codeine phosphate to remain as effective. If Codant Tablets are used repeatedly, it may become habit-forming. This is called dependence and if treatment is stopped suddenly unpleasant withdrawal symptoms may occur. Dependence on Codeine phosphate may occur after one or two weeks of treatment with the doses required to relieve pain.

**Codant contains lactose monohydrate:**

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

**3. How to take Codant**

Always take this medicine exactly as your doctor 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 Codant, 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 Codant).

**Adults:**

The usual dose is 30mg (one tablet), every six hours as needed. Do not take for longer than directed by your doctor.

**Children:**

Codant should not be used in children below the age of 12 years, due to the risk of severe breathing problems.

Children aged 12 years of above should take one to two tablets every 6 hours, as needed. Do not take more than 8 tablets in 24 hours. The maximum daily dose of codeine should not exceed 240 mg.

Codant should be used for the shortest duration necessary to relieve symptoms. 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..

**If you take more Codant than you should:**

If you think that you have taken too many tablets, contact your doctor or your hospital casualty department immediately and take this leaflet and any remaining tablets with you so that the medical staff know what you have taken.

**If you forget to take Codant**

Do not take more than one dose at a time. If you forget to take a dose then take your next dose at the usual time. Never take two doses at the same time.

**If you stop taking Codant**

If you stop taking these tablets too quickly, you may experience withdrawal symptoms such as unintentional muscle movement, restlessness and sleep disturbance, irritability, anxiety, feeling depressed, anorexia, feeling sick, being sick, diarrhoea, sweating, excess tear production, runny nose, sneezing, yawning, goose bumps, larger pupils, weakness, muscle cramps, feeling thirsty, and increase in heart rate, temperature, breathing rate and blood pressure.

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.

**All medicines can cause allergic reactions although serious allergic reactions are uncommon. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body should be reported to a doctor immediately. Difficulty in breathing and physical and psychological dependence are possible serious side effects. It is possible that you could become dependent on codeine.**

Other side-effects**Not known: frequency cannot be estimated from the available data**

- Rash and itching
- Increased sweating, redness or flushed face

- Confusion, drowsiness, feeling unwell, tiredness, vertigo, dizziness, changes in mood, abnormal imagination, restlessness/ excitement, fits, depression, headache, or nightmares, feeling of increased pressure in the head often causing severe headache
- Tolerance to codeine
- Feeling very cold
- Smaller pupils, blurred or double vision
- Abnormal heart beats, low blood pressure
- feeling faint on standing up
- Constipation, abdominal pain, feeling sick, being sick, dry mouth
- biliary spasm (causing pain in the right side of your abdomen, particularly after eating a meal, which may spread towards your right shoulder)
- Stiff muscles
- Difficulty and pain in urinating (passing water)
- Decreased sexual drive or ability to have sex (males particularly)
- Withdrawal symptoms (from stopping treatment too quickly): symptoms may include unintentional muscle movement, restlessness and sleep disturbance, irritability, anxiety, feeling depressed, loss of appetite, feeling sick, being sick, diarrhoea, sweating, excess tear production, runny nose, sneezing, yawning, goose bumps, larger pupils, weakness, muscle cramps, feeling thirsty, and increase in heart rate, temperature, breathing rate and blood pressure
- Taking a painkiller for headaches too often or for too long can make them worse.
- Inflammation of the pancreas (Pancreatitis)
- 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.

### **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](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Codant**

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 carton. Do not store above 25°C. Store in the original container in order to protect from light. 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 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 Codant contains**

The active substance is Codeine Phosphate Hemihydrate 30mg (equivalent to 23.4mg Codeine).

The other ingredients are Lactose Monohydrate, Colloidal Anhydrous Silica and Magnesium Stearate.

#### **What Codant looks like and contents of the pack:**

Codant Tablets are white, circular biconvex tablets of 5.5 mm. They are supplied in pots of 100.

#### **Marketing authorisation holder:**

Mercury Pharmaceuticals (Ireland) Ltd.,  
4045, Kingswood Road, City West Business Park,  
Co Dublin, Ireland

#### **Manufactured by:**

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