

Package leaflet: Information for the patient

Codipar® 15mg/500mg Capsules codeine phosphate hemihydrate and paracetamol

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.

The name of your medicine is Codipar® 15mg/500mg Capsules. It will be referred to as Codipar Capsules for ease hereafter.

What is in this leaflet

1. What Codipar Capsules are and what they are used for
2. What you need to know before you take Codipar Capsules
3. How to take Codipar Capsules
4. Possible side effects
5. How to store Codipar Capsules
6. Contents of the pack and other information

1. What Codipar Capsules are and what they are used for

Codipar Capsules contain paracetamol and codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

Codipar Capsules are used for the relief of mild to severe short term pain in adults. Codipar 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.

2. What you need to know before you take Codipar Capsules

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Codipar for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Codipar may cause obstructive sleep apnoea syndrome (sleep disruption due to respiratory pauses). 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 take Codipar Capsules

- if you are allergic to paracetamol, codeine or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from severe kidney or liver disease

- if you know that you metabolise very rapidly codeine into morphine
- if you are breast feeding
- if you suffer from breathing problems, for example chronic bronchitis or emphysema or are suffering from an asthma attack
- if you are taking monoamine oxidase inhibitors (MAOIs) or have been taking them within the last two weeks. MAOIs, such as phenelzine or isocarboxazid are medicines used to treat depression.
- if you have just had a head injury or suffer from increased pressure on the brain
- if you drink a lot of alcohol
- if you have recently had an operation to your gall bladder.

Codipar Capsules should not be taken by children and adolescents under 12 years of age.

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 Codipar Capsules 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 Codipar Capsules 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 Codipar Capsules, 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.
- 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 Codipar Capsules).

Sleep-related breathing disorders

Codipar Capsules 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, pharmacist or nurse before taking Codipar Capsules:

- if you are elderly
- if you have any stomach pains or other sudden problems in your abdomen (belly)
- if you are taking CNS depressants- which are substances that can slow brain activity e.g. diazepam, alprazolam, zolpidem etc.
- if you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)
- if you are suffering from inflammation or obstruction of bowel
- if you have kidney or liver problems, because the dose might need to be lower.
- if you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Codipar Capsules 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.
- if you have a condition called myasthenia gravis which weakens the muscles

Talk to your doctor or pharmacist or nurse if you experience any of the following symptoms while taking Codipar Capsules

- 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.

This product contains paracetamol. Talk to your doctor, pharmacist or nurse before taking this medicine:

- if you suffer from liver or kidney damage
- if you consume excessive alcohol
- if you take any other medicinal products affecting liver function
- if you have Glucose-6-phosphate dehydrogenase deficiency
- if you have a condition in which red blood cells are destroyed faster than they can be

made (Haemolytic anaemia)

- if you have a condition that prevents production of a molecule called glutathione
- if you suffer from dehydration
- if you suffer from chronic malnutrition
- if your weight is less than 50kg
- if you are elderly

During treatment with Codipar Capsules, tell your doctor straight away if:

- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

You should not use paracetamol frequently for a long period of time or with other paracetamol containing products. Taking paracetamol daily may cause liver problems and in such case you should contact your doctor or pharmacist immediately.

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.

Other medicines and Codipar Capsules

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. It is particularly important to tell your doctor or pharmacist if you are taking the following medicines:

- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)
- medicines to treat depression such as amitriptyline, fluoxetine, sertraline etc.
- medicines used to treat high blood pressure such as furosemide, amiloride or bendroflumethiazide
- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- medicines to treat mental illness such as chlorpromazine, haloperidol etc.
- sedatives and sleeping tablets such as temazepam and diazepam
- medicines for irregular heart beats such as mexiletine, quinine or quinidine
- drugs used to dry fluids in the mouth and lungs known as anticholinergics
- medicines to treat diarrhoea or sickness such as metoclopramide, domperidone
- medicines to treat epilepsy such as phenytoin and carbamazepine
- colestyramine, used to treat high levels of lipids in your blood, or for problems related to your bile duct
- ritonavir, used to treat HIV

- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants) such as warfarin.
- Concomitant use of Codipar Capsules 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 Codipar Capsules 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.

Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Codipar Capsules with food drink and alcohol

Do not drink alcohol whilst taking Codipar Capsules.

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 or pharmacist for advice before taking this medicine.

Pregnancy

Codipar Capsules should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born.

Breast-feeding

Do not take codeine while you are breast feeding. Codeine and morphine passes into breast milk.

Fertility

There is no data on the effects of this medicine on human fertility.

Driving and using machines

Codipar Capsules may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision. Do not drive or operate machinery if you are affected.

Information on Sodium Content:

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

3. How to take Codipar Capsules

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 Codipar Capsules, 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 Codipar Capsules). Take the capsules with a glass of water. Do not bite or chew the capsules. Do not exceed the stated dose. The dose must be limited up to four times a day

intervals of not less than six hours. Do not take with any other paracetamol-containing products. Codipar Capsules 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 feel the effect of Codipar Capsules is too strong or too weak, speak to your doctor or pharmacist. A lower dosage may be needed if you are elderly or have other medical problems. Check with your doctor about this.

Adults:

The usual dosage is two capsules every six hours as needed. You should not take more than eight capsules in any 24-hour period.

Elderly: Elderly, frail and immobile patients may require a reduced dose

Renal impairment:

If you have kidney problems your doctor may reduce the dose of paracetamol and increase the dosing interval.

Adults:

Glomerular filtration rate	Paracetamol dose
10-50 ml/min	500mg every 6 hours
<10ml/min	500mg every 8 hours

Hepatic impairment:

If you have liver problems or Gilbert's Syndrome, your doctor may reduce the dose of paracetamol and increase the dosing interval.

The maximum daily dose of paracetamol in adults should not exceed 2g/day unless directed by your doctor if:

- You weigh less than 50 kg
- You suffer from mild to moderate liver or kidney disease
- You have Gilbert's syndrome (familial non-haemolytic jaundice)
- You suffer from chronic alcoholism, malnutrition or dehydration

Use in children and adolescents

Children aged 16 years and over: The recommended dose is 2 capsules taken every 6 hours as needed. You should not take more than 8 capsules in any 24-hour period.

Children aged 12-15 years: The recommended dose is 1 capsule every 6 hours as needed with a maximum of 4 capsules in any 24-hour period.

Codipar Capsules are not recommended for children and adolescents under 12 years.

If you take more Codipar Capsules than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause irreversible liver damage. Do not exceed the stated dose.

Bring the remaining tablets and this leaflet with you so that the medical staff know what you have taken.

If you forget to take Codipar Capsules

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose then take your next dose at the usual time.

If you stop taking Codipar Capsules

Codipar Capsules can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause withdrawal symptoms such as restlessness and irritability. Your doctor will stop your capsules gradually to avoid you having these withdrawal symptoms. If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

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

The following side effects may happen due to this medicine:

Some side effects can be serious and you should tell your doctor immediately if you notice the following

- any sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting your whole body), sharp drop in blood pressure, nettle rash (urticaria) should be reported to a doctor. This could be because of anaphylactic shock or anaphylactic reaction
- a severe form of erythema multiforme (lesion and redness around the lesion) that may be extensive, involving the mucous membranes and large areas of the body. This could be because of serious skin reactions such as toxic epidermal necrolysis (TEN) or Stevens-Johnson syndrome (SJS). Very rare cases of serious skin reaction have been reported
- inflammation of the pancreas, which causes severe pain in the abdomen and back.
- a serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2) (frequency “Not known”).

The following side effects have also been reported:

Common: may affect up to 1 in 10 people

- a feeling of extra well being, or of disorientation
- light headedness, dizziness, sleepiness, headache
- difficulty in breathing
- feeling sick (nausea) and being sick (vomiting)
- stomach pains, constipation
- rash, severe itching (pruritus), hives in small areas of the skin (urticaria).

Rare: may affect up to 1 in 1,000 people

- changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting. Bruising more easily, sore throat or other signs of infection. This could be because of blood problem (such as blood dyscrasias including thrombocytopenia and agranulocytosis)

- allergic reaction which could include hives, itching, rashes, watery, red eyes.

Very rare: may affect up to 1 in 10,000 people

- occurrence of rare but severe rash after taking paracetamol can be due to acute generalised exanthematous pustulosis (type of drug reaction).

Not known: frequency cannot be estimated from the available data

- hives affecting deeper skin layers (angioedema)
- taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking tablets
- changes in level of consciousness: sluggishness, then dilatation of one or both pupils and gradual loss of consciousness could be due to brain edema
- confusion
- contraction of pupil (miosis)
- slow or weak breathing
- liver damage, especially in heavy drinkers
- occurrence of a type of drug eruption that recurs at a fixed site (or sites) after administration of paracetamol (fixed drug eruption)
- accumulation of urine within the bladder because of inability to urinate (urinary retention).
- 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.

If any of the side effects become serious, or if you notice any side effect 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 Codipar Capsules

- 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 label after EXP. The expiry date refers to the last day of that month
- do not store above 25°C. 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 Codipar Capsules contain

- The active substances are Paracetamol 500mg and Codeine Phosphate Hemihydrate 15mg

- The other ingredients are Maize Starch, Sodium laurilsulfate, Cross carmellose sodium, Talc, Magnesium Stearate, Gelatin, Titanium dioxide (E171), Erythrosine (E127), Red Iron Oxide (E172).

What Codipar Capsules look like and contents of the pack

Codipar Capsules are red (cap) and white (body) coloured hard gelatin oblong capsules with no markings.

Codipar Capsules are available in packs of 100 capsules.

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