Package leaflet: Information for the users

Codipar® 15mg/500mg Tablets
codeine phosphate/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 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.

The product is known by the name above but will be referred to as Codipar Tablets throughout the rest of this leaflet.

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

This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

This medicine has been prescribed for you for the relief of moderate pain. Codipar Tablets 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. It contains Codeine, which belongs to a group of medicines called opioid, which act as 'pain relievers'. It also contain paracetamol, which is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Codipar Tablets for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Codipar Tablets 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 Tablets if:
• you are allergic to paracetamol or codeine, or any of the other ingredients (refer to section 6 below)
• you suffer from severe kidney or liver disease
• you know that you metabolise very rapidly codeine into morphine
• you are breast-feeding
• you suffer from asthma or any other breathing problems, for example chronic bronchitis or emphysema

• 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
• you have just had a head injury or suffer from increased pressure on the brain
• you drink a lot of alcohol, or have done in the past
• you have recently had an operation to your gall bladder.

Codipar Tablets should not be given to children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Codipar Tablets if
• you are elderly or weak
• you have any stomach pains or other sudden problems in your abdomen (belly)
• you have an underactive thyroid gland
• you are prone to suffer from asthma
• you have liver, kidney or thyroid problems, because the dose might need to be lower
• you have a condition called myasthenia gravis which weakens the muscles
• you have problems with your adrenal glands (Addison's disease – your doctor will advise you)
• you suffer from an enlarged prostate gland (if male) or narrowing of your urethra (tube through which urine is passed)

Talk to your prescriber before taking this medicine if you:
• are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
• have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
• feel you need to take more of Codipar Tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

During treatment with Codipar Tablets, 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).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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). They may be at increased risk of severe side effects in case of morphine toxicity.

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 Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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:
• MAOIs used to treat depression, taken within the last 14 days (refer to "do not take if" in section 2 above)
• sedatives and sleeping tablets, e.g. temazepam and diazepam
• medicines for irregular heart beats (mexiletine, quinine or quinidine)
• drugs used to dry fluids in the mouth and lungs known as anticholinergics
• medicines to treat diarrhoea or sickness (metoclopramide, domperidone)
• medicines used to treat problems of the stomach, gall bladder, heart burn orsickness, (e.g. cimetidine, colestyramine)
• other strong painkillers called opioids
• medicines which prevent blood clotting (anticoagulants such as warfarin)
• flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of Codipar 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 Codipar 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.

Codipar Tablets can interfere with some laboratory tests used for determining some diseases.
Codipar Tablets must not be taken with any other medicines containing paracetamol or codeine. Some products which can be bought without a prescription may contain paracetamol or codeine, so always check the labels for ingredients.

Codipar Tablets with food, drink and alcohol:
Do not drink alcohol whilst taking Codipar Tablets. Swallow the tablets with a glass of water. Do not bite or chew the 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:
Do not take CodiparTablets if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Codipar Tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast feeding:
Do not take Codipar Tablets while you are breastfeeding as codeine passes into breast milk and will affect your baby.

Driving and using machines
Codipar Tablets may cause dizziness or drowsiness and you should not drive or operate machinery if you are affected this way. Codeine may disturb your vision.
The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- do not drive while taking this medicine until you know how it affects you
- it is an offence to drive if this medicine affects your ability to drive
- however, you would not be committing an offence if:
  - the medicine has been prescribed to treat a medical or dental problem and
  - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to take Codipar tablets

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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

The recommended dose is:
Adults: The recommended dose is one or two tablets every four to six hours when needed, up to a maximum of 8 tablets in any 24 hour period.
If you feel the effect of Codipar Tablets is too strong or too weak, or your symptoms persist, speak to your doctor or pharmacist. 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.
A lower dosage may be needed if you are elderly or have other medical problems.
Check with your doctor about this.

Use in children and adolescents
Children aged 16-18 years: The recommended dose is one to two tablets every 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 12–15 years: The recommended dose is one tablet every 6 hours when necessary up to a maximum of 4 tablets in 24 hours.

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

Do not take with any other paracetamol-containing products.

If you take more Codipar Tablets than you should
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Bring the remaining tablets and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Codipar Tablets
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. Never take two doses at the same time.

If you stop taking Codipar Tablets
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating, fever, weakness and muscular pains may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this product, 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 very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

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" (frequency cannot be estimated from the available data).

The following side effects are reported for CodiparTablets with the following frequency:

Common (the following may affect up to 1 in 10 people)
• feeling sick (nausea) and being sick (vomiting), constipation
• light headedness, dizziness, sleepiness
•Shortness of breath
Lying down may help these effects if they happen.

Uncommon (may affect up to 1 in 100 people)

Drug Withdrawal
When you stop taking Codipar Tablets, you may experience drug withdrawal symptoms, which include unintentional muscle movement, restlessness and difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), feeling depressed, loss of appetite, feeling or being sick, diarrhoea, shaking, shivering or 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.

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

• a feeling of extra well being, or of disorientation
• stomach pains, inflammation of pancreas
• small eye pupils, problems with vision, headaches
• slowing of the pulse

• difficulty in passing urine
• liver damage, especially in heavy drinkers
• changes in blood cells, such as low number of cells which fight infection and of cells which are involved in blood clotting.
• dependence and addiction (see section "How do I know if I am addicted?").

How do I know if I am addicted?
If you notice any of the following signs whilst taking Codipar Tablets, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again
If you notice any of these signs, it is important you talk to your prescriber

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Codipar Tablets

• keep this medicine out of the sight and reach of children
• do not use this medicineafter the expiry date which is stated on the carton. The expiry date refers to the last day of that month
• keep this medicine in a dry place
• do not store above 25ºC
• 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 Codipar Tablets contain
The active substances are paracetamol, 500mg and codeine phosphate, 15mg.
The other ingredients are maize starch, methylcellulose, talc, calcium stearate, povidone, purified water, hypromellose and macrogol 3350.

What Codipar Tablets look like and contents of the pack
Codipar Tabletsare white coated tablets available in aluminium blister packs or plastic containers with child resistant lids of 28, 30, 56, 100 or 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mercury Pharmaceuticals Ltd.,
Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufactured By
FAMAR Italia
Zambeletti, 25, 20021 Baranzate (MI)-Italy

This leaflet was last revised in March 2025

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