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MercuryPharma

Patient Information Leaflet

Codipar® 15mg/500mg Capsules

Codeine Phosphate/Paracetamol

Read all of this leaflet carefully before you start taking this medicine.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

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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. It can be used on its own or in combination with other pain killers.

Codipar Capsules are used for the relief of moderate pain. Codipar Capsules 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. 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 Capsules for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Codipar Capsules 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 capsules. Taking a painkiller for headaches too often or for too long can make them worse.

Do not take Codipar Capsules if

- you know that 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 Capsules should not be taken by children under 12 years of age.

Take special care and tell your doctor or pharmacist before taking Codipar Capsules 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 have liver, kidney or thyroid problems, because the dose might need to be lower
- 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)
- you feel you have taken Codipar Capsules for a long time. You may develop a dependence on Codipar Capsules which may be harmful.

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.

Warnings and precautions

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.

Taking other medicines

Please 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, eg. 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 or sickness (e.g. cimetidine, colestyramine)
- other strong painkillers called opioids
- medicines which prevent blood clotting (anticoagulants such as warfarin)
- Codipar Capsules 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 Capsules can interfere with some laboratory tests used for determining some diseases.

Taking Codipar Capsules with food and drink

Do not drink alcohol whilst taking Codipar Capsules.

Pregnancy and breast-feeding

Codipar Capsules should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born. Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk. Ask your doctor or pharmacist before taking any medicine.

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.

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 CAPSULES

Always take Codipar Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Take the capsules with a glass of water. Do not bite or chew the capsules.

Dose

Adults: The recommended dose is one or two capsules every four to six hours as required, up to a maximum of 8 capsules in any 24 hour period.

If you feel the effect of Codipar Capsules is too strong or too weak, 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. Do not take with any other Paracetamol containing products.

Use in children and adolescents

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

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

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

If you take more Codipar Capsules 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 capsules and this leaflet with you so that the medical staff knows what you have taken.

If you forget to take Codipar Capsules

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 Codipar Capsules

Codipar Capsules can become habit forming. This is called dependence, if you stop taking your medicine suddenly it can cause 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Codipar Capsules can cause side effects, although not everybody gets them.

Possible side effects are

- feeling sick (nausea) and being sick (vomiting)
- light headedness, dizziness, sleepiness
- shortness of breath
- stomach pains, constipation.

Lying down may help these effects if they happen.

Other side effects include

- allergic reactions, including skin rashes and itching of the skin
- a feeling of extra well being, or of disorientation
- 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
- problems with breathing.

If a pain killer is used too long for headaches, it can make them worse. 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 Codipar Capsules after 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 25°C.

Medicines should not be disposed of via wastewater. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Codipar Capsules contain

- the active substances are paracetamol 500mg and codeine phosphate 15mg
- the other ingredients are maize starch, sodium lauryl sulfate, cross carmellose sodium, purified talc, magnesium stearate, gelatin, titanium dioxide (E171), erythrosine (E127) and 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 30, 32 or 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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