

PACKAGE LEAFLET – INFORMATION FOR THE USER
Co-codamol 15 mg/500 mg Film-coated Tablets
(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 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

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1. What Co-codamol 15 mg/500 mg Film-coated Tablets are and what they are used for

Co-codamol 15 mg/500 mg Film-coated Tablets are one of a group of medicines called analgesics or painkillers. They are used to relieve moderate pain. This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

Co-codamol can be used in adults and adolescents 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 Co-codamol 15 mg/500 mg Film-coated Tablets

Do not take Co-codamol 15 mg/500 mg Film-coated Tablets:

- If you are allergic to codeine phosphate hemihydrate, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- If you are suffering from increased pressure on the brain or a head injury.
- If you have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- If you are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). Ask your doctor or pharmacist if you are not sure what types of medicine you are taking.
- If you consume excessive amounts of alcohol on a regular basis.
- If you are breast-feeding.
- If you have recently had gall bladder, liver or bile duct (biliary tract) surgery.
- If you are having (or have recently had) a severe but short-lasting asthma attack (acute asthma).
- If you know that you metabolise very rapidly codeine into morphine.

Talk to your doctor if any of the above apply to you.

Do not use this product 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.

Co-codamol should not be given to children under 12 years of age.

Warnings and precautions

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

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 medicine should be avoided if you have a biliary tract disorder (gall bladder or bile duct disease).

Talk to your doctor or pharmacist before taking Co-codamol 15 mg/500 mg Film-coated Tablets:

- If you are elderly and/or in poor health
- If you suffer from an enlarged prostate
- If you suffer from any bowel problems
- If you suffer from Addison's disease
- If you are dehydrated
- If you have glucose-6 phosphate dehydrogenase deficiency
- If you have a disorder which causes red blood cells to be destroyed faster than they are made (haemolytic anaemia)
- If you have Gilbert's Syndrome
- If you have an under active thyroid (hypothyroidism)
- If you suffer from myasthenia gravis (a disease characterised by weakness of certain groups of muscles)
- If you suffer from low blood pressure
- If you have glutathione deficiency (a metabolic disorder which may lead to difficulty in breakdown of paracetamol).

Check with your doctor before use if you have liver or kidney problems, are underweight (<50 kg), become malnourished or regularly drink alcohol as this may increase your risk of liver damage. You may need to reduce the amount of paracetamol that you take or avoid using this product altogether.

If any of the above apply to you, it is important that you speak to your doctor or pharmacist before taking Co-codamol 15 mg/500 mg Film-coated Tablets and they will decide what to do. It may still be safe for you to take Co-codamol 15 mg/500 mg Film-coated Tablets.

- 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.

During treatment with Co-codamol, tell your doctor straight away:

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).

Children and adolescents

Co-codamol should not be given to children under 12 years of age.

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 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 Co-codamol 15 mg/500 mg Film-coated Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:

- medicines called Monoamine Oxidase Inhibitors (MAOIs) used to treat depression, or have taken them in the last two weeks (see section 2 “Do not take Co-codamol 15 mg/500 mg Film-coated Tablets...”). MAOIs are medicines such as moclobemide, phenelzine and tranylcypromine.
- medicines for depression, anxiety, other medicines known as tranquillisers, or hypnotics (medicines to help you sleep). You may experience more drowsiness if you take these medicines with codeine.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- cholestyramine (medicine for high cholesterol levels or diarrhoea). The absorption of paracetamol is reduced by this medicine.
- domperidone or metoclopramide (medicines to stop you feeling sick or vomiting). The speed of absorption of paracetamol may be increased by these medicines.
- anticoagulants, e.g. warfarin (medicine to prevent blood clots). There may be an increased risk of bleeding caused by prolonged regular use of paracetamol.
- medicines that you have bought yourself such as cough/cold remedies or other painkillers. Many of these will contain paracetamol and/or codeine and should not be taken while you are taking Co-codamol 15 mg/500 mg Film-coated Tablets.
- paracetamol clearance is increased in women taking oral contraceptives.
- potential hepatotoxic drugs or drugs that induce liver enzymes may increase the toxicity of paracetamol e.g. barbiturates or tricyclic antidepressants.
- excretion of paracetamol may be affected when given with probenecid.

Concomitant use of Co-codamol 15 mg/500 mg Film-coated 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 Co-codamol 15 mg/500 mg Film-coated 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.

Co-codamol 15 mg/500 mg Film-coated Tablets with food and alcohol

You should avoid alcohol when taking this product.

Food has no influence on Co-codamol 15 mg/500 mg Film-coated 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 or pharmacist for advice before taking this medicine.

Co-codamol 15 mg/500 mg Film-coated Tablets should not be used during pregnancy as it can affect the baby and can cause breathing problems when the baby is born.

Do not take Co-codamol 15 mg/500 mg Film-coated Tablets while you are breast-feeding. Codeine and morphine passes into breast milk.

No available data on fertility.

Driving and using machines

Co-codamol 15 mg/500 mg Film-coated Tablets may make you feel dizzy or drowsy. Do not drive or use machines if you are affected this way.

This medicine can affect your ability to drive.

Do not drive while taking this medicine until you know how it affects you. It may be an offence to drive while under the influence of this medicine.

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

Important information about some of the ingredients of Co-codamol 15 mg/500 mg Film-coated Tablets

This medicine contains lecithin (derived from soya). If you are allergic to peanut or soya, do not use this medicine.

3. How to take Co-codamol 15 mg/500 mg Film-coated Tablets

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

Adults:

Take 2 tablets with water, every 4 hours as needed.

- Do not take more frequently than every 4 hours.
- Do not take more than 8 tablets in 24 hours (equivalent to 4 g paracetamol and 120 mg codeine phosphate).

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

Kidney Impairment: It is recommended, when giving paracetamol to patients with kidney impairment, to reduce the dose and to increase the minimum interval between each administration to at least 6 hours.

Adults:

<i>Glomerular filtration rate</i>	<i>Dose</i>
10-50ml/min	500mg every 6 hours
<10ml/min	500mg every 8 hours

Liver Impairment: In patients with impaired liver function or Gilbert's Syndrome, the dose must be reduced or the dosing interval prolonged.

The maximum daily dose of paracetamol should not exceed 2 g/day in patients over 16 years of age in the following situations unless your doctor gives you different advice:

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

Adolescents 16-18 years of age:

Take 2 tablets with water, every 6 hours as needed.

- Do not take more frequently than every 6 hours.
- Do not take more than 8 tablets in 24 hours (equivalent to 4 g paracetamol and 120 mg codeine phosphate).
- Do not take more than the recommended dose.

Adolescents 12-15 years of age:

Take 1 tablet with water, every 6 hours as needed.

- Do not take more frequently than every 6 hours.
- Do not take more than 4 tablets in 24 hours (equivalent to 2 g paracetamol and 60 mg codeine phosphate).
- Do not take more than the recommended dose.

This medicine should not be taken by children under 12 years of age, due to the risk of severe breathing problems.

Doctors sometimes prescribe different doses to these. Read the pharmacist's label, it will tell you exactly how many you should take.

This medicine should be taken orally (by mouth). The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

This medicine should only be taken when necessary. Do not take more than the stated dose and do not take for more than three days. If the pain does not improve after three days, talk to your doctor for advice.

If you take more Co-codamol 15 mg/500 mg Film-coated Tablets than you should

It is always important to follow the dose recommended on the label. Talk to a doctor immediately if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious and irreversible liver damage.

If you forget to take Co-codamol 15 mg/500 mg Film-coated Tablets

If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take Co-codamol 15 mg/500 mg Film-coated Tablets any more. However, if you still suffer from pain take your dose as soon as you remember and then carry on as before. It is important that you do not take a double dose to make up for the forgotten dose.

If you stop taking Co-codamol 15 mg/500 mg Film-coated Tablets

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.

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.

If you experience any of these symptoms, please tell your doctor or pharmacist immediately:

- allergic reaction (skin rash, itching, swelling or shortness of breath)
- serious skin reactions (very rare cases of serious skin reactions have been reported)
- sudden pain in the upper part of your abdomen, if you have previously had your gall bladder removed
- signs of bronchospasm such as difficulty in breathing, shortness of breath, wheezing, tightness in the chest (more likely to occur in those with asthma who are sensitive to medicines used to treat inflammation, such as aspirin).

The following side effects have been reported:

- feeling sick or vomiting
- dizziness or drowsiness

Lying down may relieve these effects.

- slow heart beat
- narrowing of your pupils
- constipation
- stomach pains
- light-headedness
- headache
- slow or weak breathing
- hallucination
- confusion or changes in your mood
- bladder problems
- itchy skin or itchy, raised rash (hives)
- low blood cell counts (platelets and white blood cells) but these were not necessarily related to paracetamol
- 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 (cannot be estimated from the available data).

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:

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Co-codamol 15 mg/500 mg Film-coated Tablets

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 and blister foil. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice that the pack or any of the tablets are damaged.

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 Co-codamol 15 mg/500 mg Film-coated Tablets contain

The active substances are codeine phosphate hemihydrate and paracetamol. Each tablet contains 15 mg of codeine phosphate hemihydrate and 500 mg of paracetamol.

The other ingredients are pregelatinised starch, povidone (K-30), microcrystalline cellulose PH102, maize starch, crospovidone XL 10, colloidal anhydrous silica, magnesium stearate, polyvinyl alcohol part hydrolyzed, titanium dioxide, talc, lecithin (soya), xanthan gum.

What Co-codamol 15 mg/500 mg Film-coated Tablets look like and contents of the pack

Co-codamol 15 mg/500 mg Film-coated Tablets are white to off-white oblong-shaped, biconvex, film-coated tablets with break line on one side and plain on other side.

Co-codamol 15 mg/500 mg Film-coated Tablets are available in packs of 100 tablets.

Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

Manufacturer

Meiji Pharma Spain, S.A., Avda. De Madrid, 94., 28802, Alcala de Henares (Madrid), Spain.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland Co-codamol 15 mg/500 mg Film-coated Tablets

Malta Co-codamol 15 mg/500 mg Film-coated Tablets

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