

PACKAGE LEAFLET: INFORMATION FOR THE USER
Co-codamol 30mg/500mg
Effervescent Tablets
Codeine phosphate hemihydrate/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 Co-codamol 30mg/500mg Effervescent Tablets. It will be referred to as Co-codamol Effervescent Tablets for ease hereafter.

What is in this leaflet

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2. What you need to know before you take Co-codamol Effervescent Tablets
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1. What Co-codamol Effervescent Tablets Are And What They Are Used For

Co-codamol Effervescent Tablets 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. Co-codamol Effervescent Tablets are used for the relief of mild to severe short term pain. Co-codamol 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 Co-codamol Effervescent Tablets

Do not take with any other paracetamol-containing products. Do not take for longer than directed by your prescriber. Do not use Co-codamol for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids as Codeine in Co-codamol 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 Co-codamol Effervescent Tablets if:

- you are allergic to paracetamol, codeine phosphate or any of the other ingredients of this medicine (listed in section 6)
- you suffer from breathing problems, for example chronic bronchitis or emphysema or are suffering an asthma attack

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

Co-codamol Effervescent Tablets should not be taken by children under 12 years of age.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Co-codamol Effervescent Tablets if:

- you have any stomach pains or other sudden problems in your abdomen (belly)
- you are elderly
- you have liver or kidney problems, because the dose might need to be lower
- your prostate is larger than normal or you have a narrowing of your urethra (tube through which urine is passed)
- you feel you have taken Co-codamol Effervescent Tablets for a long time. You may develop a dependence on Co-codamol Effervescent Tablets which may be harmful
- you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Co-codamol Effervescent Tablets 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.

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 must 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). 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 Effervescent Tablets

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:

- Medicines to treat depression such as amitriptyline, fluoxetine, sertraline etc.
- Medicines used to treat high blood pressure such as furosemide, amiloride or bendroflumethazide
- 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, e.g. chlorpromazine, haloperidol etc
- 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 to treat epilepsy (e.g. 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 Co-codamol Effervescent 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 Effervescent 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.

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

Co-codamol Effervescent Tablets with food, drink and alcohol

Do not drink alcohol whilst taking Co-codamol Effervescent 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.

Pregnancy

Co-codamol Effervescent Tablets should not be used during pregnancy as they can affect the baby and can cause breathing problems when the baby is born.

Breastfeeding

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:

Co-codamol Effervescent 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.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected.

There is further information for patients who are intending to drive in Great Britain - go to

<https://www.gov.uk/drug-driving-law>

Important information about some of the ingredients of Co-codamol Effervescent Tablets:

This medicine contains sorbitol (487mg per tablet), which is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains 413 mg sodium in each tablet. This should be taken into consideration by patients on a controlled sodium (salt) diet.

3. How To Take Co-codamol Effervescent Tablets

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

Method of administration

The tablets must be put in a glass of water and allowed to completely dissolve. Drink the resulting solution immediately. Do not chew or bite your tablets.

Dose:

Adults:

The usual dosage is one or two tablets every six hours as needed. You should not take more than 8 tablets in 24 hours. If you feel the effect of Co-codamol Effervescent Tablets 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.

Older people:

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

The recommended dose for children aged 16 and over is two tablets taken every six hours. You should not take more than eight tablets in any 24-hour period.

The recommended dose for children aged 12 to 15 years is one tablet taken every six hours, up to a maximum of four tablets in any 24-hour period.

Co-codamol Effervescent Tablets are not recommended for children under 12 years.
Do not take with any other paracetamol-containing products.

If you take more Co-codamol Effervescent Tablets 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 delayed, serious liver damage. Bring the remaining tablets and this leaflet with you so that the medical staff know what you have taken.

If you forget to take Co-codamol Effervescent 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.

If you stop taking Co-codamol Effervescent Tablets:

Co-codamol Effervescent Tablets can become habit forming. This is called dependence (addiction), if you stop taking your medicine suddenly it can cause withdrawal symptoms such as restlessness and irritability. Your doctor will stop your tablets gradually to avoid you having these withdrawal symptoms. If you find you need to use this product all the time, it is important to consult your doctor. 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 with 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
- 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 Blood dyscrasias including thrombocytopenia and agranulocytosis)
- severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (Pancreatitis)
- very rare cases of serious skin reaction have been reported.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

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
- slow or weak breathing,
- feeling sick (nausea), vomiting, constipation, stomach pain
- itching (pruritus), rash, hives in small areas of the skin (urticaria).

Rare (may affect up to 1 in 1,000 people)

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

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 this medicine
- confusion, drowsiness
- small eye pupils
- difficulty in breathing
- liver damage, especially in heavy drinkers
- difficulty in passing urine, inability to empty the bladder.

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 (see details below)

United Kingdom

The Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

or

Ireland

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517;
Website: www.hpra.ie;
e-mail: medsafety@hpra.ie.

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

5. How To Store Co-codamol Effervescent Tablets

- Keep this medicine out of the sight and reach of children
 - Do not use Co-codamol Effervescent Tablets after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.
 - Do not store above 25°C. Keep the tubes tightly closed in order to protect from moisture.
- 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. Content of the pack and other information

What Co-codamol Effervescent Tablets contain:

- The active substances are codeine phosphate hemihydrate 30mg and paracetamol 500mg.
- The other ingredients are sodium hydrogen carbonate, sodium carbonate anhydrous, citric acid anhydrous, sodium docusate, sorbitol, saccharin sodium, dimeticone, sodium benzoate, macrogol 6000 and spray-dried natural grapefruit flavour.

What Co-codamol Effervescent Tablets look like and contents of the pack:

Co-codamol Effervescent tablets are white circular tablets with a score line on one face, although your tablets are scored they must not be halved as they will not give an equal dose.

Co-codamol Effervescent tablets are available in aluminium: polyethylene foils strips packs of 100 effervescent tablets (25 strips of 4 tablets) or in polypropylene tubes.

Each tube contains 16 tablets and 6 tubes are packed in cardboard containers to give a pack size of 96 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mercury Pharmaceuticals Ltd.,

Capital House, 85 King William Street, London, EC4N 7BL, UK

Manufactured By:

Unither Industries,

ZI du Malcourlet, 03800 Gannat, France.

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