

Package Leaflet: Information for the User
Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets
Paracetamol/Codeine Phosphate Hemihydrate

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:

1. What Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets are and what they are used for
2. What you need to know before you take Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets
3. How to take Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets
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1. What Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets are and what they are used for

This medicine contains Paracetamol/Codeine. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers raised temperatures). Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

This medicine can be used in patients over 16 years 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 Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets

Do not take this medicine if:

- you are allergic to paracetamol or codeine, or any of the other ingredients of this medicine (listed in section 6)
- you suffer from acute asthma or 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 are an alcoholic or have recently consumed a lot of alcohol
- you have recently had an operation to your gall bladder or a similar operation
- in children and adolescents (0-18 years of age) for pain relief after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome
- you know that you metabolise very rapidly codeine into morphine
- you are about to give birth, are at risk of premature birth or are breastfeeding (see section Pregnancy, breast-feeding and fertility)

Warnings and precautions

Do not take with any other paracetamol containing products.

Talk to your doctor or pharmacist before taking this medicine if:

- you have any stomach pains or other sudden problems in your abdomen (belly)
- you are prone to suffer from asthma
- you are elderly
- you have liver or kidney problems, including alcoholic liver disease 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 have bowel problems
- you have low blood pressure (hypotension)
- you have multiple sclerosis
- you have a history of drug or alcohol abuse
- you have a condition known as glucose-6-phosphate dehydrogenase (G6PD) deficiency because of the risk of a particular form of anaemia (low number of red blood cells)
- you have glutathione deficiency
- you have Gilbert's syndrome (liver condition in which the liver doesn't properly process bilirubin) (familial non-haemolytic jaundice)
- you have chronic malnutrition or dehydration
- you weigh less than 50kg

Taking a painkiller for headaches too often or for too long can make them worse.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms such as restlessness and irritability, once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.

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.

Other medicines and Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription, including herbal 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, paroxetine, bupropion etc.
- Cinacalcet, used to treat hyperparathyroidism
- The hypotensive effects of antihypertensive agents, including diuretics, may be potentiated by codeine.
- MAOIs used to treat depression, taken within the last 14 days (refer to “do not take if” in section 2 above)
- Drugs which make you sleepy, including alcohol and barbiturates.
- Medicines for irregular heartbeats (mexiletine, quinine or quinidine)
- Morphine products, used to treat severe pain
- Methadone, used to treat opioid addiction and also severe pain
- Benzodiazepines, used to treat anxiety, due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.
- Certain cough medicines
- Drugs used to dry fluids in the mouth and lungs known as anticholinergics
- Medicines to treat diarrhoea or sickness (metoclopramide, domperidone), buprenorphine, nalbuphine, pentazocine , naltrexone
- Medicines to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine)
- Chloramphenicol, rifampicin, antibiotics used to treat infection .
- St John’s Wort (*Hypericum perforatum*)
- Colestyramine, used to treat high levels of lipids in your blood, or for problems related to your bile duct.
- Oral contraceptives (“the pill”)
- Medicines which prevent blood clotting (anticoagulants such as warfarin).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

This medicine 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.

Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets with food, drink and alcohol

You should not drink alcohol whilst taking this medicine. This is due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.

Use in Children and adolescents

This medicine should not be taken by children below the age of 16 years.

Use in children and adolescents after surgery

Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets 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 and adolescents with breathing problems

Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Children 16 to 18 years of age who have breathing problems should not take this product. This includes breathing problems while sleeping or other lung problems.

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

This medicine 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 this medicine while you are breast feeding. Codeine and morphine passes into breast milk.

Fertility

There is no information concerning the effect of this medicine on fertility.

Driving and using machines

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

Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets contains sorbitol and sodium

Sorbitol: This medicine contains 487 mg sorbitol in each effervescent tablet.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugar or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Information on sodium content

This medicine contains 413 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 20.65 % of the recommended maximum daily dietary intake of sodium for an adult. The maximum recommended daily dose of this medicinal product contains 3304mg sodium (main component of cooking/table salt). This is equivalent to 165.2% of the adult recommended maximum daily dietary intake for sodium.

Talk to your doctor or pharmacist if you need more effervescent tablet daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets

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

Dosage:

The recommended dose is one or two tablets every four hours as needed. You should not take more than 8 tablets in 24 hours. If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

The maximum daily dose should not exceed 4 tablets per day unless your doctor gives you different advice if:

- You weigh less than 50 kg
- You suffer from chronic alcoholism, malnutrition or dehydration

Elderly

Recommended dose: 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

This medicine should not be taken by children below the age of 16 years.

Adolescents aged 16 to 18 years should take this medicine every 6 hours, as needed, according to the doctor's instructions. The maximum daily dose should not exceed 4 g of paracetamol and 240 mg of codeine. Do not take more than 8 tablets in 24 hours.

This combination medicine is not suitable for children aged between 12-15 years. For children aged between 12-15 years, other formulations and dose strengths are more appropriate. Alternatively, the medicines can be prescribed separately.

Patients with impaired kidney- or liver function or Gilbert's syndrome

A lower dosage or prolonged dosage interval may be needed in patients with impaired kidney or liver function or Gilbert's syndrome, (liver condition in which the liver doesn't properly process bilirubin). Check with your doctor about this.

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.

Duration of treatment

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. Do not take this medicine longer than as directed by your doctor.

If you take more Paracetamol/Codeine 500 mg / 30 mg Effervescent 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 know what you have taken.

If you forget to take Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets

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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets

This medicine 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 product, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets and see a doctor or go to a hospital straight away if:

- You have skin rash, swelling or itching, difficulty in breathing, feeling dizzy. These symptoms could be signs of an allergic reaction.
- You experience blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.
- You have a severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body. Also a feeling of being generally unwell, fever, chills and aching muscles. This may be something called 'Toxic epidermal necrolysis'. Very rare cases of serious skin reactions have been reported.
- You have difficulty breathing, wheezing, coughing and shortness of breath (more likely in asthmatics sensitive to aspirin or other NSAIDs such as ibuprofen).

Taking codeine regularly for a long time can lead to addiction, which might cause you feel restless and irritable when you stop the tablets.

Other side effects include:**Codeine:****Very common (may affect more than 1 in 10 people)**

- dizziness, sleepiness, headache*
- feeling sick (nausea), being sick (vomiting)
- constipation, stomach pain
- skin rashes or itching (pruritus)
- You have extreme feelings of joy and happiness (euphoria)
- You have extreme feelings of sadness and depression (dysphoria)

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

- confusion
- small eye pupils, problems with vision
- difficulty in passing urine
- You have a seizure
- You have dry mouth
- You have a ringing in your ears (tinnitus)

- You have blurred vision due to the pupil of the eye becoming smaller (myosis)
- You start breathing more quickly than normal and the skin around your mouth is a blue colour. This could be symptoms of respiratory depression.

Paracetamol:

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

- abnormal vision, Haemorrhage (bleeding), abdominal pain, diarrhoea, nausea, vomiting, dizziness, fever, reduction of irritability or agitation (sedation) platelet disorders (clotting disorders), stem cell disorders (disorders of the blood forming cell in the bone marrow), abnormal liver function, liver failure, hepatic necrosis (death of liver cells), jaundice, overdose and poisoning, tremor, headache, depression, confusion, hallucinations, sweating, feeling lousy (malaise)

Very rare (may affect up to 1 in 10000 people):

- Hepatotoxicity (damage caused to the liver), Thrombocytopenia (reduction in blood platelets, which increases the risk of bleeding or bruising), Leukopenia (frequent infections due to poorly functioning white blood cells or decrease in white blood cells), Neutropenia (reduced neutrophil count in blood), Agranulocytosis (severe decrease in white blood cells which may lead to severe infections), Hemolytic anemia (abnormal breakdown of red blood cells, which may cause weakness or pale skin), Hypoglycemia (low levels of glucose in the blood), Cloudy urine and kidney disorders

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

- Anaemia (decrease in red blood cells), gastrointestinal effects, vertigo, accumulation of fluid in the voice box. You have difficulty breathing, wheezing, tightness in the chest (bronchospasm), You have no appetite, have abdominal pain and feel generally unwell and your skin and/or whites of your eyes are a yellowish colour. These could be symptoms of cytolytic hepatitis, a serious liver disease, Excess acid in the blood caused by too much pyroglutamic acid due to low glutathione levels.

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 at: 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 Paracetamol/Codeine 500 mg / 30 mg Effervescent 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 the blister or tube after “EXP”. The expiry date refers to the last day of that month.
- *For the polypropylene tubes:*
Store in the original polypropylene tubes. Keep the tubes tightly closed in order to protect from moisture. Use within 2 years of first use.
- *For the foil strips:*
This medicine does not require any special storage conditions.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

6. Contents of the pack and other information

What Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets contain

- The active substances are Paracetamol, 500 mg and Codeine Phosphate Hemihydrate, 30 mg.
- The other ingredients are sodium hydrogen carbonate, sodium carbonate anhydrous, citric acid anhydrous, sodium docusate, sorbitol, saccharin sodium, dimeticone, sodium benzoate, macrogol 6000 and natural grapefruit flavour.

What Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets looks like and contents of the pack

Paracetamol/Codeine 500 mg / 30 mg 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.

Paracetamol/Codeine 500 mg / 30 mg Effervescent Tablets are available in:

- aluminium/polyethylene foils strips of 4, 8, 16, 32 and 100 effervescent tablets
- polypropylene tubes of 8, 16, 32 and 96 effervescent tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised in March 2024

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