

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

Paracetamol and 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:

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1. What Paracetamol Codeine 500 mg / 30 mg Effervescent Tablets are and what they are used for

This medicine contain paracetamol and 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 Paracetamol Codeine 500 mg / 30 mg Effervescent Tablets if:

- you are allergic to paracetamol or codeine, 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 drink a lot of alcohol
- you have recently had an operation to your gall bladder
- you know that you metabolise very rapidly codeine into morphine
- you are breastfeeding

This medicine should not be given to children and adolescents (0-18 years of age) for pain relief after removal of their tonsils or adenoids due to the risk of obstructive sleep apnoea syndrome.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracetamol and Codeine 500 mg / 30 mg, effervescent tablets 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, 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 Paracetamol Codeine 500 mg / 30 mg Effervescent Tablets for a long time. You may develop a dependence on this medicine 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.

Long-term treatment

Taking codeine (an active ingredient of Paracetamol Codeine 500 mg / 30 mg Effervescent Tablets) regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop taking the tablets.

Children and adolescents

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

Furthermore it should not be used

- for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.
- in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.
- in children below the age of 12 years, due to the risk of severe breathing problems.

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. 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 bendroflumethiazide
- 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 heartbeats (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)
- Rifampicin (an antibiotic)
- 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.
- Ritonavir, used to treat HIV
- Other strong painkillers called opioids
- Medicines which prevent blood clotting (anticoagulants such as warfarin).

Paracetamol Codeine 500 mg / 30 mg Effervescent 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.

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

Do not drink alcohol whilst taking Paracetamol Codeine 500 mg / 30 mg 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

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 Paracetamol Codeine 500 mg / 30 mg Effervescent Tablets on fertility.

Driving and using machines

This medicine may cause dizziness or drowsiness and you should not 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.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicinal product contains 17.9 mmol (413 mg) sodium per tablet. To be taken into consideration by patients on a controlled sodium (salt) 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.

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.

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.

Codeine:

The following side effects are serious. Talk to your doctor straight away if you notice them:

Very common (may affect more than 1 in 10 people)

- shortness of breath
- feeling overly elated or depressed

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

- confusion
- small eye pupils, problems with vision
- slow or weak breathing
- yellowing of the skin or whites of the eyes (symptoms of liver damage)
- difficulty in passing urine

Other side effects include:

Very common (may affect more than 1 in 10 people)

- light headedness, dizziness, sleepiness, headache*
- feeling sick (nausea), being sick (vomiting)
- constipation, stomach pain
- skin rashes or itching

*If a pain killer is used too long for the treatment of headaches, it can make them worse.

Paracetamol:

Very rare cases of serious skin reactions have been reported.

- accumulation of fluid in the voice box including an itchy rash, throat swelling (severe allergic reaction),
- swelling on the face, mouth, hands (angioedema)

You should stop taking this medicine and see your doctor immediately if you experience symptoms like:

- Serious skin disease causing rash, severe blistering, skin peeling and sores. These side effects are very rare
- Difficulty breathing, Wheezing, Coughing and shortness of breath (more likely in asthmatics sensitive to aspirin or other NSAIDs). Frequency is not known.

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

- abnormal vision, simple skin rash or urticaria (dark red rash on the skin), Haemorrhage (bleeding), abdominal pain, diarrhea, 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, pruritus (itching), 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), problems with the way your liver works (liver alteration), anuresis (inability to urinate), gastrointestinal effects, vertigo

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 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.
- *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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To request a copy of this leaflet in Braille, large print or audio format then please contact the marketing authorisation holder at the address (or telephone, fax, email) above.