

Package Leaflet: Information for the patient



Paracetamol & Codeine 500mg/8mg Effervescent Tablets

Codeine phosphate hemihydrate and paracetamol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Important things you should know about Paracetamol & Codeine 500mg/8mg Effervescent Tablets

- This medicine can only be used for the short term treatment of acute, moderate pain such as headaches, migraine, neuralgia, toothache, painful menstrual periods and rheumatic pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three days you should see your doctor or pharmacist for advice.
- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than three days it can make them worse.
- The name of your medicine is Paracetamol & Codeine 500mg/8mg Effervescent Tablets (called Paracetamol & Codeine Effervescent Tablets throughout this leaflet).
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.

What is in this leaflet

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1. What Paracetamol & Codeine Effervescent Tablets are and what they are used for

Paracetamol & Codeine Effervescent Tablets contain codeine phosphate hemihydrate and paracetamol. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol & Codeine Effervescent Tablets are used in adults and children over 12 years of age for the short term treatment of acute moderate pain caused by headaches, migraine, toothache, neuralgia, period pain and rheumatic pains when other painkillers such as paracetamol, ibuprofen or aspirin alone have not worked. Wait at least 4 hours after you last took other painkillers before taking this medicine.

2. What you need to know before you take Paracetamol & Codeine Effervescent Tablets

- This medicine contains codeine which can cause addiction if you take it continuously for more than three days. This can give you withdrawal symptoms from the medicine when you stop taking it.

- **This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.**
- **If you take a painkiller for headaches for more than three days it can make them worse.**

Warnings and precautions

Do not take Paracetamol & Codeine Effervescent Tablets and tell your doctor if:

- You are allergic to the active substances or any of the other ingredients in your medicine (listed in Section 6). Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.
- You are taking medicines to treat depression called MAOIs (Monoamine Oxidase Inhibitors) or have taken them in the last 14 days. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine (see 'Other medicines and Paracetamol & Codeine Effervescent Tablets').
- The person going to take the tablets is under 12 years of age. Paracetamol & Codeine Effervescent Tablets must not be given to children under 12 years of age.
- You are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome.
- You know that you metabolise very rapidly codeine into morphine.
- You are breastfeeding or planning to breastfeed.

Do not take Paracetamol & Codeine Effervescent Tablets if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Paracetamol & Codeine Effervescent Tablets.

Take special care and check with your doctor before taking Paracetamol & Codeine Effervescent Tablets if:

- You have severe kidney or liver problems.
- You have a liver problem caused by alcohol.
- You suffer from seizures.
- You have a condition called myasthenia gravis which weakens the muscles.

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

Children and adolescents over 12 years of age

Use in children and adolescents after surgery

Paracetamol & Codeine 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 with breathing problems

Paracetamol & Codeine Effervescent Tablets are not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

This medicine is not recommended in adolescents over 12 years-old with breathing problems.

Other medicines and Paracetamol & Codeine Effervescent 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 or have taken within the last two weeks:

- Monoamine oxidase inhibitors (MAOIs) such as moclobemide and phenelzine used in the treatment of depression.
 - Medicines which make you drowsy or sleepy (CNS depressants and benzodiazepines) such as medicines used to treat anxiety or anaesthetics.
 - Medicines for depression such as dosulepin, mirtazapine (Tricyclic) or chlorpromazine (phenothiazines).
 - Medicines known as tranquillisers, or hypnotics.
 - Sleeping tablets, sedatives and some antihistamines.
- You may experience more drowsiness if you take these medicines with Paracetamol & Codeine Effervescent Tablets.

Paracetamol & Codeine Effervescent Tablets contain paracetamol. Do not take anything else containing paracetamol while taking this medicine.

This includes some painkillers, cough and cold remedies. It also includes a wide range of other medicines available from your doctor and more widely in shops.

Tell your doctor or pharmacist if you are taking any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Paracetamol & Codeine Effervescent Tablets can affect the way some other medicines work or other medicines can affect the way Paracetamol & Codeine Effervescent Tablets work.

- Medicines used to thin the blood such as warfarin.
- Chloramphenicol - an antibiotic used for infections.
- 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.
- Metoclopramide or domperidone - used to stop you feeling sick (nausea) or being sick (vomiting).
- Colestyramine - for lowering blood cholesterol levels.
- The oral contraceptive pill.

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

Pregnancy and breastfeeding

Talk to your doctor before taking these tablets if:

- You are pregnant, think you may be pregnant or plan to get pregnant.
- You are planning to breastfeed. Do not take Paracetamol & Codeine Effervescent Tablets while you are breastfeeding. Codeine passes into breast milk.

Driving and using machines

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive whilst 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 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 Effervescent Tablets contain sodium and sorbitol

Sodium: The maximum recommended daily dose of this medicinal product contains 3348.8mg sodium (found in table salt). This is equivalent to 167.44% of the adult recommended maximum daily dietary intake for sodium. Talk to your pharmacist or doctor if you need Paracetamol & Codeine Effervescent Tablets on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

Sorbitol (E420): This medicine contains 100mg sorbitol in each tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars 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.

3. How to take Paracetamol & Codeine Effervescent Tablets

Always take this medicine exactly as instructed in this leaflet. Check with your doctor or pharmacist if you are not sure.

- **Do not take for more than three days. If you need to use this medicine for more than three days you should speak to your doctor or pharmacist.**
- **Do not take more than the recommended dose.**
- **Dissolve the effervescent tablets in a glass of water before taking.**

Adults and the elderly: 2 tablets every 4 to 6 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 16 to 18 years: 1 to 2 tablets every 6 hours when necessary up to a maximum of 4 doses in 24 hours.

Children aged 12 to 15 years: 1 tablet every 6 hours when necessary up to a maximum of 4 doses in 24 hours.

Children under 12 years: Paracetamol & Codeine Effervescent Tablets should not be given to children below 12 years of age due to the risk of severe breathing problems.

If you take more Paracetamol & Codeine 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.
- Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you forget to take Paracetamol & Codeine Effervescent Tablets

If you forget to take a dose at the right time, take it as soon as you remember. However do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses for adults and 6 hours for children and adolescents aged 12 to 18 years.

If you stop taking Paracetamol & Codeine Effervescent Tablets

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

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:

Important side effects you should know about Paracetamol & Codeine Effervescent Tablets:

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

Stop taking Paracetamol & Codeine Effervescent Tablets and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to Paracetamol & Codeine Effervescent Tablets.
- You get serious skin reactions. Very rare cases have been reported.
- You have a fit (seizure).
- You have difficulty breathing and you feel dizzy.

Talk to your doctor straight away if you notice the following serious side effect:

- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis). This is a very rare side effect.

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

- Constipation
- Feeling sick (nausea), being sick (vomiting), dry mouth
- Dizziness, light-headedness, drowsiness, confusion
- Feeling overly happy (euphoria)
- A feeling of unease or dissatisfaction
- Excessive constriction (shrinking) of the pupil of your eye
- Difficulty in passing water (urine)
- Becoming dependent on codeine
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia).

How do I know if I am addicted?

If you take this medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. However, if the following apply to you it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, but you feel better once taking the medicine again.

Reporting of side effects

If you get any side effects, talk to your doctor or 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paracetamol & Codeine Effervescent Tablets

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

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 Paracetamol & Codeine Effervescent Tablets contain

The active substances of Paracetamol & Codeine Effervescent Tablets are codeine phosphate hemihydrate and paracetamol. Each tablet contains 8 mg of codeine phosphate hemihydrate and 500 mg of paracetamol.

The other ingredients are citric acid, sorbitol (E420), sodium hydrogen carbonate, povidone, simeticone, sodium carbonate, saccharin sodium, macrogol 6000.

What Paracetamol & Codeine Effervescent Tablets look like and contents of pack

Paracetamol & Codeine Effervescent Tablets are white to off-white, round, flat, bevelled edge tablets, plain on both sides. The diameter of the tablet is approximately 25.4 mm.

They come in Surlyn strip packs containing 24 or 32 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Accord, Barnstaple, EX32 8NS, UK

Manufacturer:

Accord Healthcare Limited, Sage house, 319 Pinner Road, Harrow, HA1 4HF, United Kingdom

Distributed by The Boots Company PLC, Nottingham, NG2 3AA.

This leaflet was last revised in February 2024.

Artwork reference: TP03271