

350 mm

← Fold from here

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

- **Very rare** (may affect up to 1 in 10,000 people): Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis).
- **Not known** (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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

- **Not known** (frequency cannot be estimated from the available data): 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, 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.

GB00 0000 0 0000000
UKP-002
TP03392

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 the 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 January 2025.



Package Leaflet: Information for the patient

Boots 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

1. What Paracetamol & Codeine Effervescent Tablets are and what they are used for
2. What you need to know before you take Paracetamol & Codeine Effervescent Tablets
3. How to take Paracetamol & Codeine Effervescent Tablets
4. Possible side effects
5. How to store Paracetamol & Codeine Effervescent Tablets
6. Contents of the pack and other information

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.

1. What Paracetamol & Codeine Effervescent Tablets are and what they are used for
2. What you need to know before you take Paracetamol & Codeine Effervescent Tablets
3. How to take Paracetamol & Codeine Effervescent Tablets
4. Possible side effects
5. How to store Paracetamol & Codeine Effervescent Tablets
6. Contents of the pack and other information

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.

GB00 0000 0 0000000
UKP-002
TP03392

Back side

Front side

← Fold from here

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 have problems passing water or prostate problems
- You have a bowel problem such as colitis or Crohn's disease or a blockage of your bowel
- You have a condition called myasthenia gravis which weakens the muscles
- You suffer from hypothyroidism
- You have a disease of the adrenal gland called Addison's disease
- You are taking a benzodiazepine
- You are elderly
- You suffer from seizures.

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

During treatment with Paracetamol & Codeine Effervescent Tablets, 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 flucoxacin (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 flucoxacin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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 tranquilisers, or hypnotics
- Sleeping tablets, sedatives and some antihistamines.

You may experience more drowsiness if you take these medicines with Paracetamol & Codeine Effervescent Tablets. Concomitant use of Paracetamol & Codeine 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 Paracetamol & Codeine 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.

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
 - Flucoxacin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2)
 - 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.

Paracetamol & Codeine Effervescent Tablets with alcohol

You should not drink alcohol while you are taking these tablets. This is because Paracetamol & Codeine Effervescent Tablets can change the way alcohol affects you.

Pregnancy and breast-feeding

- 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 breast-feed. Do not take Paracetamol & Codeine Effervescent Tablets while you are breast-feeding. 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 3348.5 mg 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 100 mg 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 described in this leaflet, or as your doctor or pharmacist have told you. 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.**
- **Do not take more than the recommended dose.**
- **Do not take more than the recommended dose.**

Always take this medicine exactly as described in this leaflet, or as your doctor or pharmacist have told you. 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.

Do not take more than the recommended dose.

Do not take more than the recommended dose.

Do not take more than the recommended dose.

Do not take more than the recommended dose.

GB00 0000 0 0000000
UKP-002
TP03392

Inner side 1

Inner side 2

← Glue Area