

Package leaflet: Information for the patient

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 500 mg/8 mg/30 mg effervescent tablets

paracetamol/codeine phosphate hemihydrate/caffeine

[For medicines available only on prescription:]

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.

What is in this leaflet

1. What Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord is and what it is used for
2. What you need to know before you take Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord
3. How to take Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord
4. Possible side effects
5. How to store Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord
6. Contents of the pack and other information

1. What Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord is and what it is used for

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord contains two pain-relieving substances (paracetamol and codeine) that work in different ways and caffeine which enhance the pain-relieving effects of paracetamol.

Paracetamol has both pain-relieving and fever-reducing effects.

Codeine belongs to a group of medicines called opioid analgesics which also act to relieve pain.

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord can be used in patients over 18 years of age for the short-term relief of acute, 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 Phosphate Hemihydrate/Caffeine Accord Effervescent Tablets

Do not take Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord

- if you are allergic to paracetamol, codeine, caffeine or any of the other ingredients listed (See Section 6)
- if you have acute asthma (if you have suffered from recent asthma attacks)
- in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome;
- if you know that you metabolise very rapidly codeine into morphine
- if you are breastfeeding.
- if you are under 12 years of age for the symptomatic treatment of cough and/or cold;
- if you suffer from chronic constipation
- treatment with MAO inhibitors or within two weeks after their continuation
- In respiratory depression, head injuries and raised intra cranial pressure

Warning and precautions

Talk to your doctor or pharmacist before taking this medicine

- Have an enlarged prostate (difficulty passing water).
- Have any bowel disorders.
- Have any liver or kidney problems.
- Have heart or blood pressure problems.
- have been told by your doctor that you have an intolerance to some sugars.
- have recently had gall bladder surgery or a similar operation.
- have chronic alcoholism.
- have Gilbert's Syndrome (familial non-haemolytic jaundice)
- are taking other medicines that can affect the liver.
- have glucose-6-phosphate dehydrogenase deficiency.
- have haemolytic anaemia.
- are dehydrated.
- have had poor diet such that the diet causes health problems.
- weigh less than 50kg.
- are elderly.

They may reduce the dose or increase the time interval between doses of your medicine.

Talk to your doctor or pharmacist before taking <Invented tablet>:

- have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances

Taking codeine (an active ingredient of this medicine) regularly for a long time can lead to addiction and misuse, which may result in overdose and/or death.

Do not take this medicine longer than needed. Do not give this medicine to anyone else.

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.

Special warnings about addiction

This product contains codeine. This medicine should only be taken when necessary. Do not take more than the stated dose and do not take every day for more than 3 days unless told to do so by your doctor. Prolonged regular use, except under medical supervision, may lead to 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 or think you are suffering from withdrawal symptoms, it is important to consult your doctor or pharmacist.

Children and adolescents

This medicine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome. Codeine is not recommended in children or adolescents with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

During treatment with Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord, tell your doctor straight away if:

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 flucloxacillin (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

flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord

Tell your pharmacist or doctor before taking Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord if you are taking, have recently taken or might take any other medicines, especially:

- medicines that you have bought yourself such as cough/cold remedies and other painkillers. Many of these will contain paracetamol and/or codeine and must not be taken while you are taking Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord
- if you are taking or have taken within the last 2 weeks medicines prescribed by your doctor for the treatment of depression or anxiety, or medicines known as tranquilisers (including monoamine oxidase inhibitors-MAOIs).
- medicines used to relax you or to help you sleep (such as benzodiazepines).
- medicine for high cholesterol levels or for the treatment of diarrhoea (cholestyramine).
- medicines to stop you feeling sick or vomiting (domperidone or metoclopramide).
- medicines to prevent blood clots (such as warfarin).
- medicines for the treatment of gout (probenecid).
- medicines for eye infections (chloramphenicol).
- anticonvulsants and medicines used to treat epilepsy (such as barbiturates).
- oral contraceptive steroids.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of this medicine 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 this medicine 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 Phosphate Hemihydrate/Caffeine Accord with food, drink and alcohol

- do not drink alcohol when taking this medicine.
- avoid excessive intake of caffeine containing products such as coffee, tea and some canned drinks.

Pregnancy and breast-feeding

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

Do not take this medicine if you are pregnant or think you may be pregnant unless your doctor has advised you to do so.

Brest-feeding

Do not use this medicine if you are breastfeeding, it passes into breast milk and may harm the baby.

Driving and using machines

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord may make you feel drowsy. You should not drive, operate machinery or ride a bicycle until you know how they affect you.

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord contains sodium and sorbitol:

- This medicine contains 419 mg (18.22 mmol) sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 21% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your pharmacist or doctor if you need more effervescent tablet daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.
- This medicine contains 100 mg sorbitol in each effervescent tablets. 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 Phosphate Hemihydrate/Caffeine Accord

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

The recommended dose is

Adults (Individuals 18 years of age and older)

1-2 tablets every 4-6 hours 3 times daily. In case of more severe pain 1-2 tablets every 4-6 hours 4 times daily can be taken. Do not take more than 4 doses in 24 hours, equivalent to 8 tablets.

The dose should not be repeated more frequently than every 4 hours.

Elderly patients may require a reduced dose or frequency of dosing.

How to take the medicine

Tablets should be dissolved in at least half a glass of water. The resulting solution should be drunk immediately.

Do not exceed the stated dose.

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.

If you take more Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 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.

The symptoms can include: nausea, vomiting, anorexia, pale skin, and abdominal pain, or patients may be asymptomatic.

If you forget to take Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord

Do NOT take a double dose to make up for a forgotten dose. You must allow at least 4 hours between doses.

4. Possible side effects

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

Prolonged regular use, except under medical supervision, may lead to addiction and result in withdrawal symptoms, such as restlessness and irritability once the drug is stopped. If you need to take the medicine for longer periods of time or you need to take more than the recommended dose or feel irritable and restless when you stop taking the medicine, you may be addicted. In any of these apply to you, it is important that you talk to your doctor.

This medicine may make you feel dizzy or drowsy. You may also feel sick or vomit. These effects may be relieved by lying down. You may also become constipated. You may experience problems with your blood which means that you may bleed or bruise easily (known as thrombocytopenia) or which makes it more likely that you may get an infection (known as agranulocytosis).

If you have previously had gall bladder removal surgery and experience severe abdominal pain, nausea and vomiting, or if you have previously experienced breathing problems with aspirin or other non-steroidal anti-inflammatories and experience a similar reaction with this product, stop taking this medicine and tell your doctor immediately.

Taking any type of pain reliever for headaches for a long period of time can make them worse. If this situation is experienced or suspected, stop taking this medicine and talk to your doctor.

Some of the following side effects may occur:

- allergic reactions such as skin rash or itching, sometimes with breathing problems, or swelling of the lips, tongue, throat or face.
- unusual bleeding or bruising under the skin
- skin rash or peeling of the skin which may be accompanied by mouth ulcers.
- severe skin reactions such as severe blisters and bleeding in the lips, eyes, mouth, nose and genitals and formation of blisters containing pus.
- blood disorders including low platelet count (making you slow to heal and bruise easily) and low white blood cell count (making you more likely to get infections).
- cloudy urine or urinary retention.
- nervousness and tremor.
- hallucinations and nightmares.
- fast or irregular heartbeat.
- blurred vision.
- facial flushing.
- constipation.

These effects go away once you stop taking the medicine. If any of these effects occur, or get serious, or if you notice any other side effect not listed in this leaflet, stop taking this medicine, and tell your doctor or pharmacist immediately.

Frequency 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).

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

HPRRA 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 Phosphate Hemihydrate/Caffeine Accord

- 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 strip after EXP. 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 Phosphate Hemihydrate/Caffeine Accord contains

- The active substances are paracetamol, codeine phosphate hemihydrate and caffeine. Each effervescent tablet contains 500 mg paracetamol, 8 mg codeine phosphate hemihydrate and 30 mg caffeine.
- The other ingredients are citric acid (E330), sorbitol (E420), sodium hydrogen carbonate (E 500 (II)), povidone (E 1201), simeticone, sodium carbonate, anhydrous (E 500 (I)), saccharin sodium (E 954) and macrogol (E 1521) (refer section 2).

What Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord looks like and contents of the pack

Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord are white to off white, round effervescent tablets. The diameter of the tablets is approximately 26 mm. Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord are available in strips containing 4, 8, 10, 12, 16, 20, 24, 32, 40, 60 or 80 effervescent tablets. Not all pack sizes may be marketed.

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Netherlands	Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 500 mg/8 mg/30 mg effervescent tablets
Slovakia	CETAFEN RAPID 500 mg/8 mg/30 mg sumiva tableta
Ireland	Paracetamol/Codeine Phosphate Hemihydrate/Caffeine Accord 500 mg/8 mg/30 mg effervescent tablets

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