

Package leaflet: Information for the user

Paracetamol/Codeine Accord 500 mg / 30 mg effervescent tablets

Paracetamol and codeine phosphate hemihydrate

Read all of this leaflet carefully before you start using 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of this medicine is Paracetamol and Codeine 500 mg / 30 mg effervescent tablets but within this leaflet it will be referred to as Paracetamol/Codeine Accord.

What is in this leaflet

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

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

Paracetamol/Codeine Accord belongs to a group of medicines called analgesics (painkillers), and is used in adult patients (18 years of age and older) for the relief of *severe pain*.

Paracetamol/Codeine Accord can be used in patients older than 12 years of age for the treatment of acute moderate pain which is not considered to be relieved by other analgesics such as paracetamol or ibuprofen (alone).

This product contains paracetamol and codeine.

Paracetamol is an analgesic that can be used to relieve pain.

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

2. What you need to know before you take Paracetamol/Codeine Accord

Do not take Paracetamol/Codeine Accord

- if you are allergic to paracetamol or codeine or any of the other ingredients of this medicine (listed in section 6.1)
- if you have asthma or severe breathing problems
- if you have recently had a head injury
- if you have recently had gall bladder surgery or a similar operation
- if you have raised pressure in the brain
- if you are an alcoholic or have recently consumed a large amount of alcohol
- for pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome

- you are taking monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days
- If you know that you metabolise very rapidly codeine into morphine.
- If you are breastfeeding

Do not take this medicine if any of the above apply to you.

Warnings and precautions

Sleep-related breathing disorders

Paracetamol/Codeine Accord can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Paracetamol/Codeine Accord can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Paracetamol/Codeine Accord if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Paracetamol/Codeine Accord, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You might feel that you need to carry on taking your medicine, even when it doesn’t help to relieve your pain
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’)

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Paracetamol/Codeine Accord).

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.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Do not take with any other paracetamol containing products.

Talk to your doctor before taking Paracetamol/Codeine Accord

- If you have prostate problems (e.g. difficulty in passing water)
- If you have bowel problems
- If you have kidney or liver problems including alcoholic liver disease
- If you have low blood pressure (hypotension)
- If you have multiple sclerosis
- If you have a history of drug or alcohol abuse
- If 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)
- If you have glutathione deficiency
- If you have Gilbert's syndrome (familial non-haemolytic jaundice)
- If you have chronic malnutrition or dehydration
- If you weigh less than 50 kg
- If you are elderly.

During treatment with Paracetamol/Codeine Accord 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 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)
- If you experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

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.

Children and adolescents

Do not give this medicine to children under 12 years of age because it is unlikely to be safe.

Use in children and adolescents after surgery

Paracetamol/Codeine Accord 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 Accord is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Children 12 to 18 years of age who have breathing problems should not take this product. This includes breathing problems while sleeping or other lung problems.

Other medicines and Paracetamol/Codeine Accord

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because this medicine can affect the way some other medicines work. Also, some other medicines can affect the way this medicine works.

Tell your doctor if you are taking any of the following medicines:

- Metoclopramide, domperidone (used to treat nausea and vomiting)
- Buprenorphine, nalbuphine, pentazocine, naltrexone used to reduced analgesic effect due to competitive receptor blockade
- Quinidine, used to treat irregular heartbeat
- Fluoxetine, paroxetine, bupropion, amitriptyline, sertraline used to treat depression
- Cinacalcet, used to treat hyperparathyroidism
- Colestyramine (used to treat high blood cholesterol (fat) levels)
- Chloramphenicol, flucloxacillin, rifampin, antibiotics used to treat infection
- Benzodiazepines, used to treat anxiety, due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.
- Morphine products, used to treat severe pain
- Methadone, used to treat opioid addiction and also severe pain
- Certain cough medicines
- Oral contraceptives (“the pill”)
- Drugs which make you sleepy, including alcohol and barbiturates
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).
- Medicine which prevent blood clotting (anticoagulants such as warfarin).
- Medicine to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine)
- The hypotensive effects of antihypertensive agents, including diuretics, may be potentiated by codeine
- MAOIs used to treat depression, taken within the last 14 days
- Drugs used to dry fluids in the mouth and lungs known as anticholinergics
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).

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

Paracetamol/Codeine Accord with alcohol

You should not drink alcohol while you are taking these tablets. This is due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take this medicine during labour as it can affect the baby and can cause breathing problems when the baby is born.

Breast-feeding

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

Driving and using machines

You may feel dizzy or sleepy while taking this medicine. You may also have problems with your vision. If this happens, do not drive or use any tools or machines.

Paracetamol/Codeine Accord contains sodium and sorbitol

- **Sorbitol:** This medicine contains 100 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 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.
- **Sodium:** This medicinal product contains 419 mg sodium (main component of cooking/table salt) per effervescent tablet. This is equivalent to 21% recommended maximum daily dietary intake for sodium for an adult. Talk to your pharmacist or doctor if you need this medicine on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to take Paracetamol/Codeine Accord

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Paracetamol/Codeine Accord, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Paracetamol/Codeine Accord).

Adults (18 years and over):

Take one or two tablets every 6 hours.

Do not take more than 8 tablets in 24 hours.

Adolescents aged 16 to 18 years:

One to two tablets every 6 hours to a maximum of three doses in any 24 hours. Do not exceed 6 tablets in 24 hours.

Children aged 12 to 15 years:

Take one tablet every 6 hours. Do not take more than 4 tablets in 24 hours.

Children aged less than 12 years:

This medicine should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Elderly

Elderly patients may be prescribed a lower dose.

Renal impairment

Both the dosing and the interval between each dose may be adjusted. Always take the medicine as your doctor told you.

Hepatic impairment

In patients with impaired liver function or Gilbert's syndrome, the dose must be reduced or the dosing interval prolonged.

Do not take more than 4 tablets in 24 hours if

- You weigh less than 50 kg
- You suffer from mild to moderate liver or kidney disease
- You have Gilbert's syndrome (familial non-haemolytic jaundice)
- You suffer from chronic alcoholism, malnutrition or dehydration

How to take the medicine

Dissolve the effervescent tablets in at least half a glass of water (about 100-125 ml water).

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.

Paracetamol/Codeine Accord should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

Whilst taking this medicine you should not take any other medicines which contain paracetamol. Do not exceed the recommended dose. Do not take for longer than your doctor tells you to.

If you take more Paracetamol/Codeine Accord than you should

Immediate medical advice should be sought in the event of overdose, even if you feel well, because of the risk of irreversible liver damage.

If you forget to take Paracetamol/Codeine Accord

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 6 hours between doses.

If you stop taking Paracetamol/Codeine Accord

Long term usage of this medicine may lead to tolerance and dependence. If you have taken regular daily doses of this medicine for a long time, do not increase the dose or suddenly stop treatment without discussing this with your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional.

Important side-effects you should know about Paracetamol/Codeine Accord

- 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 Accord and see a doctor or go to a hospital straight away if:

- You develop a 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.

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

- 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.

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)
- extreme feelings of joy and happiness (euphoria)
- extreme feelings of sadness and depression (dysphoria)

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

- confusion
- difficulty in passing urine
- seizure
- dry mouth
- ringing in your ears (tinnitus)
- blurred vision due to the pupil of the eye becoming smaller (miosis)
- 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.
- 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.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).
- Problem affecting a valve in the intestines (sphincter of Oddi dysfunction).

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 Accord

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

Do not use this medicine after the expiry date stated on the strip and the carton after (EXP). The expiry date refers to the last day of that month.

Store below 25°C.

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

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

Ask your pharmacist how to dispose of medicines no longer required. Do not dispose of medicines by flushing down a toilet or sink or by throwing out with your normal household rubbish. This will help protect the environment.

6. Contents of the pack and other information

What Paracetamol/Codeine Accord contains

The active substances of Paracetamol/Codeine Accord are codeine phosphate hemihydrate and paracetamol. Each tablet contains 500 mg of paracetamol and 30 mg of codeine phosphate hemihydrate.

The other ingredients are citric acid (E 330), sorbitol (E420), sodium hydrogen carbonate (E 500 (II)), povidone(E 1201), simeticone, sodium carbonate (E 500 (I)), saccharin sodium (E 954), polyethylene

glycol (E 1521) and Lemon Flavor (contains Maize maltodextrin, Acacia gum (gum arabic, E414), Natural flavouring substances, Flavouring preparations, Flavouring substances, Alpha-tocopherol (E307)).

What Paracetamol/Codeine Accord look like and contents of pack

Paracetamol/Codeine Accord are white to off-white, round, flat, bevelled edge tablets, plain on both sides. The diameter of tablet is approximately 26 mm.

Surlyn strip (plain 4ply paper based laminated strip foil 50gsm outer side paper/12gsm PE extrusion / 9 µ Aluminium / 23 gsm surlyn inner side) packs {Surlyn is a copolymer of ethylene and methacrylic acid used as packaging material}: containing : 4, 8, 10, 12, 14, 16, 20, 24, 28, 30, 32, 36, 40, 50, 60, 90 and 100 tablets.

For France: 4, 8, 10, 12, 14, 16, 20, 24 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Cork, T45 K857,
Ireland

Manufacturer

Laboratori Fundació Dau,
C/ C, 12-14 Pol. Ind. Zona
Franca, Barcelona, 08040, Spain

Accord Healthcare B.V.

Winthontlaan 200,
Utrecht, 3526 KV
Netherlands

Pharmadox Healthcare Ltd.

KW20A Kordin Industrial Park,
Paola, PLA3000, Malta

Accord Healthcare Polska Sp. zo.o.,

ul. Lutomińska 50, Pabianice, 95-
200, Poland

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

Name of the member state	Name of the medicine
Finland	Paracetamol/Codeine Accord
France	PARACETAMOL/CODEINE ACCORD 500mg/30mg, comprimé effervescent
Ireland	Paracetamol/Codeine Accord 500 mg/30 mg, effervescent tablet
Italy	PARACETAMOLO E CODEINA ACCORD HEALTHCARE
Norway	Paracetamol/ codeine phosphate hemihydrate Accord
Sweden	Paracetamol/Codeine Accord

The Netherlands	Paracetamol/Codeine Accord 500 mg/30 mg, bruistablet
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