

PACKAGE LEAFLET

Package leaflet: Information for the patient

Paracetamol/Codeine phosphate hemihydrate Accord 500 mg/30 mg tablets paracetamol/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

1. What Paracetamol/Codeine phosphate hemihydrate Accord is and what it is used for
2. What you need to know before you take Paracetamol/Codeine phosphate hemihydrate Accord
3. How to take Paracetamol/Codeine phosphate hemihydrate Accord
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1. What Paracetamol/Codeine phosphate hemihydrate Accord is and what it is used for

Paracetamol/Codeine phosphate hemihydrate 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 phosphate hemihydrate Accord can be used in patients from 12 years of age and older for the short-term relief of moderate pain that is not relieved by other painkillers 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 phosphate hemihydrate Accord

Do not take Paracetamol/Codeine phosphate hemihydrate Accord:

- 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
- If you know that you metabolise very rapidly codeine into morphine
- If you are impending childbirth or in case of risk of premature birth
- If you are breastfeeding
- If you are allergic to codeine, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- If you have acute asthma or severe breathing problems
- If you have 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 taking monoamine oxidase inhibitors (used to treat depression) or have taken them in the last 14 days
- If you are chronic alcoholic
- If you are associated with sodium oxybate.

Warnings and precautions

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.

Do not take with any other paracetamol containing product.

Talk to your doctor or pharmacist before taking Paracetamol/Codeine phosphate hemihydrate 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
- If you are taking other medicines containing paracetamol

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.

Other medicines and Paracetamol/Codeine phosphate hemihydrate 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 Paracetamol/Codeine phosphate hemihydrate Accord can affect the way some medicines work. Also, some medicines can affect the way Paracetamol/Codeine phosphate hemihydrate Accord works.

Please check with your doctor if you are taking any of the following:

- Metoclopramide (used to treat nausea and vomiting)
- Domperidone
- Buprenorphine
- Nalbuphine
- Pentazocine
- Naltrexone
- Quinidine, used to treat irregular heartbeat
- Fluoxetine, paroxetine, bupropion, used to treat depression
- Cinacalcet, used to treat hyperparathyroidism
- Colestyramine (used to treat high blood cholesterol (fat) levels)
- Chloramphenicol, flucloxacillin, rifampicin, 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
- Drugs used to thin the blood (e.g. warfarin).
- 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.

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

Taking Paracetamol/Codeine phosphate hemihydrate Accord with food and drink

You should not drink alcohol while you are taking Paracetamol/Codeine phosphate hemihydrate Accord. This is due to an increased risk of sedation, breathing difficulties or even coma, when both are taken together.

Use in children and adolescents

Use in children and adolescents after surgery

Paracetamol/Codeine phosphate hemihydrate 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 and adolescents with breathing problems

Paracetamol/Codeine phosphate hemihydrate 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.

Pregnancy and breastfeeding

Do not take Paracetamol/Codeine phosphate hemihydrate Accord if you are pregnant, think you may be pregnant or are trying to get pregnant without first talking to your doctor or pharmacist.

Do not take Paracetamol/Codeine phosphate hemihydrate Accord while you are breastfeeding. Codeine and morphine pass into breast milk and is harmful for the child.

Driving and using machines

You may feel dizzy or sleepy while taking Paracetamol/Codeine phosphate hemihydrate Accord. You may also have problems with your vision. If this happens, do not drive or use any tools or machines.

Paracetamol/Codeine phosphate hemihydrate Accord contains sodium

This medicine contains less than 1mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to take Paracetamol/Codeine phosphate hemihydrate 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. Your doctor will tell you how much Paracetamol/Codeine phosphate hemihydrate Accord you must take.

Adults (18 years and over):

Take one to two tablets every 6 hours to a maximum of four doses in any 24 hours. Do not take more than 8 tablets in 24 hours. Elderly patients may be prescribed a lower dose.

Adolescents aged 16 to 18 years:

Dose should be established on an individual basis depending on body weight. Doctor will prescribe the medicine accordingly.

One to two tablets every 6 hours to a maximum of four doses in any 24 hours. Do not take more than 8 tablets in 24 hours.

Adolescents aged 12 to 15 years:

Dose should be established on an individual basis depending on body weight. Doctor will prescribe the medicine accordingly.

One tablet every 6 hours to a maximum of four doses in any 24 hours. Do not take more than 4 tablets in 24 hours.

Children aged less than 12 years:

Paracetamol/Codeine phosphate hemihydrate Accord should not be taken due to the risk of severe breathing problems.

Kidney problem:

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

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 (A mild condition in which the liver doesn't properly process bilirubin) (Familial non-haemolytic jaundice)
- You suffer from chronic alcoholism, malnutrition or dehydration

How to take the medicine

Swallow the tablet.

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 have kidney failure, leave at least 6-8 hours between doses.

Whilst taking Paracetamol/Codeine phosphate hemihydrate Accord you should not take any other medicines which contain paracetamol.

Do not exceed the stated dose. Do not take for longer than your doctor tells you to.

If you take more Paracetamol/Codeine phosphate hemihydrate 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. The symptoms of liver damage usually appear after a few days. It is therefore important that you contact a doctor immediately if you have taken too high a dose, even if you are feeling fine.

If you forget to take Paracetamol/Codeine phosphate hemihydrate 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 phosphate hemihydrate Accord

Long term usage of Paracetamol/Codeine phosphate hemihydrate Accord may lead to tolerance and dependence. If you have taken regular daily doses of Paracetamol/Codeine phosphate hemihydrate Accord 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.

You should **stop taking** Paracetamol/Codeine phosphate hemihydrate Accord and see your doctor immediately if you experience symptoms of the severe side effects angioedema, Stevens-Johnson syndrome or toxic epidermal necrolysis (frequency not known, cannot be estimated from available data).

Antioedema

- With symptoms such as: skin rash, swelling or itching, difficulty in breathing, feeling dizzy. These symptoms could be signs of an allergic reaction.

Stevens-Johnson syndrome'

- With symptoms such as: blistering or bleeding of the skin around the lips, eyes, mouth, nose and genitals. Also, flu-like symptoms and fever.

Toxic epidermal necrolysis

- With symptoms such as: 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.

Other side effects

Very rare (may affect up to 1 in 10,000 people):

- You get infections or bruise more easily than usual. This could be because of a blood problem (such as leukopenia, neutropenia or thrombocytopenia)
- Stomach pain, which may reach to your back. This could be a sign of inflammation of the pancreas (pancreatitis).

Not known (cannot be estimated from available data):

- constipated
- feel sick (nauseous) or start being sick (vomiting)
- headache dizziness, light headedness, drowsiness, and confusion
- difficulty in passing water (urine)
- a seizure
- dry mouth
- itchy skin rash (pruritus)
- ringing in your ears (tinnitus)
- difficulty breathing, wheezing, and tightness in the chest (bronchospasm)
- extreme feelings of joy and happiness (euphoria) or extreme feelings of sadness and depression (dysphoria)
- blurred vision due to the pupil of the eye becoming smaller (myosis)
- breathing more quickly than normal and the skin around your mouth is a blue colour. This could be symptoms of respiratory depression.
- tiredness, your skin and/or whites of your eyes are a yellowish colour. These could be symptoms of haemolytic anaemia
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 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 blister after EXP. The expiry date refers to the last day of that month.

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 you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Paracetamol/Codeine phosphate hemihydrate Accord contains

The active substances are paracetamol and codeine phosphate hemihydrate. Each tablet contains 500 mg paracetamol and 30 mg codeine phosphate hemihydrate.

The other ingredients are silica, colloidal anhydrous (E551), croscarmellose sodium (E468), copovidone, cellulose microcrystalline (E460), talc (E553b), magnesium stearate (E570) and povidone.

What Paracetamol/Codeine phosphate hemihydrate Accord looks like and contents of the pack

Paracetamol/Codeine phosphate hemihydrate Accord are white, oval (17 mm x 8.5 mm) biconvex tablets, marked 'LK' on one side.

Paracetamol/Codeine phosphate hemihydrate Accord are available in PVC//Alu/Paper blisters containing 10, 16, 20, 30, 50, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland
Euro House, Euro
Business Park, Little
Island, Cork, T45 K857,
Ireland

Manufacturer

Accord Healthcare Polska Sp. z.o.o.
Ul. Lutomińska 50, 95-200,
Pabianice, Poland

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

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

- LT : Codeine phosphate hemihydrate/Paracetamol Accord 30 mg/500 mg plėvele dengtos tabletės
- EE : Paracetamol/codeine Accord
- LV : Paracetamol/codeine Accord
- NO : Paracetamol/Codeine Accord

SE : Paracetamol/Codeine Accord
FR : PARACETAMOL/CODEINE ACCORD 500 mg/30 mg, comprimé
IT : Paracetamolo e Codeina Accord
IE : Paracetamol/Codeine phosphate hemihydrate Accord 500 mg/30 mg tablets

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