

APO-Paracetamol/Codeine 500/30

Contains the active ingredients, paracetamol and codeine phosphate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Paracetamol/Codeine 500/30 tablets. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking APO-Paracetamol/Codeine 500/30 against the benefits this medicine is expected to have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

APO-Paracetamol/Codeine 500/30 is used to relieve moderate to severe pain and fever.

APO-Paracetamol/Codeine 500/30 contains paracetamol and codeine. Paracetamol and codeine work together to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever.

Your doctor may have prescribed this medicine for another use.

Ask your doctor or pharmacist if you have any questions about why the medicine has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take this medicine :

- If you are allergic to paracetamol or codeine or any of the ingredients listed under "Product Description" at the end of this leaflet.
The symptoms of an allergic reaction may include a rash, asthma attack or hay fever.
- If you have or have had any of the following medical conditions:
 - Acute breathing difficulties such as bronchitis, unstable asthma or emphysema
 - Glucose-6-phosphate dehydrogenase deficiency (an enzyme deficiency)
 - Diarrhoea caused by poisoning or antibiotics
 - CYP 2D6 ultra-rapid metaboliser
- If you have alcohol dependence.
- During the third trimester of pregnancy.
- During labour especially if the baby is premature.
This medicine contains codeine, which may produce withdrawal effects in the newborn baby.
- If you are breastfeeding or planning to breastfeed.

The medicine passes into breast milk and may affect the baby.

- In children (aged below 18 years) who have undergone tonsillectomy and/or adenoidectomy to treat obstructive sleep apnoea.
- After the expiry date (EXP) printed on the pack.
If you take it after the expiry date it may have no effect at all, or worse, have an entirely unexpected effect.
- If the packaging is torn or shows signs of tampering.
- To treat any other complaint unless your doctor says it is safe.
- APO-Paracetamol/Codeine 500/30 is not recommended for children under 12 years.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - Any other medicines
 - Aspirin or any other NSAID medicine
 - Any other substances, such as foods, preservatives or dyes
 - Any ingredients listed under "Product Description" at the end of this leaflet
2. You have or have had any medical conditions, especially the following:
 - Lung, liver or kidney problems
 - Difficulty breathing, wheezing, chronic cough, asthma, or other chronic breathing conditions
 - A history of drug dependence, including alcohol dependence

- You drink large quantities of alcohol
 - Diarrhoea caused by poisoning
 - Recent stomach, intestine or urinary tract surgery
 - Irritable bowel syndrome
 - Prostate problems
 - Under active thyroid gland or problems with your adrenal glands
 - Fits or seizures
 - Head injury
3. You are currently pregnant or you plan to become pregnant.
Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Taking other medicines

You should also tell your doctor about any other medicines that you have bought without a prescription from either your pharmacy, supermarket or health food shop.

Tell your doctor if you are using any other medicines, including any of the following medicines:

- Any medicine causing sleepiness or drowsiness
- Tranquillisers (medicines for anxiety and nerves)
- Medicines used to treat depression
- Medicines which thin the blood
- Medicines to treat epilepsy
- Other pain relief medication
- Medicines used to treat high blood pressure
- Medicines used to relax muscles
- Medicines used to treat diarrhoea, nausea or vomiting
- Chloramphenicol (antibiotic used to treat ear and eye infections)
- Rifampicin and zidovudine (medicines for infection)

These medicines may be affected by APO-Paracetamol/Codeine 500/30 or may affect how well APO-Paracetamol/Codeine 500/30 works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

How to take this medicine

The label on your pack of APO-Paracetamol/Codeine 500/30 will tell you how to take your medicine and how often.

If you are unsure about the directions ask your doctor or pharmacist.

Do not take more than the dose your doctor or pharmacist has directed.

How much to take

The dosage recommended by the doctor may be different to the recommended dosage.

The recommended dose of APO-Paracetamol/Codeine 500/30 is:

Adults: 1 tablet for mild to moderate pain. 2 tablets for severe pain.

This dosage may be repeated in 4-6 hours if necessary.

Do not take more than 8 tablets in 24 hours.

Do not take more than the recommended dose.

Taking more than the recommended dose may cause liver damage.

Talk to your doctor about pain control if the medicine is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

Children (12+ years): Half (1/2) a tablet.

This dosage may be repeated in 4-6 hours if necessary.

Children should not take more than 3 tablets in 24 hours.

How to take it

Swallow the tablets with water.

The directions given to you by your doctor or pharmacist may be different from the information in this leaflet. If you are unsure what dose to take ask your pharmacist or doctor.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much APO-Paracetamol/Codeine 500/30.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers of these places handy.

If you take too many tablets you may feel nauseous, light headed, dizzy or drowsy.

While you are taking this medicine

Things you must do

Take APO-Paracetamol/Codeine 500/30 exactly as your doctor has prescribed.

Tell all your doctors, dentists and pharmacists that you are taking APO-Paracetamol/Codeine 500/30.

Tell your doctor if you become pregnant while taking APO-Paracetamol/Codeine 500/30.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Adults should not take more than 8 tablets a day.

Children should not take more than 3 tablets a day.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Taking more than the recommended dose may cause liver damage.

Codeine may be habit forming.

Do not give this medicine to anyone else.

Things to be careful of

APO-Paracetamol/Codeine 500/30 may cause dizziness or drowsiness in some people, especially after the first dose.

If affected do not drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or drowsy. Children should not ride bikes if affected and should be supervised to avoid potential harm.

Do not drink alcohol.

Drinking alcohol increases the likelihood of becoming drowsy.

APO-Paracetamol/Codeine 500/30 may be habit forming if taken in high doses for extended periods of time.

Ask your doctor or pharmacist if you are concerned about this.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking APO-Paracetamol/Codeine 500/30.

Like other medicines, APO-Paracetamol/Codeine 500/30 can cause some side effects. If they occur, they are most likely minor and

temporary. However, sometimes they are serious and need medical treatment.

If you have any questions, ask your doctor or pharmacist.

Tell your doctor if you notice any of the following.

This list includes the more common side effects. Mostly, these are mild:

- Constipation
- Nausea
- Vomiting
- Stomach pain
- Dizziness
- Drowsiness
- Skin rashes
- Sweating

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention.

Mostly, these side effects are rare:

- Shortness of breath
- Mouth ulcers, fever and sore throat
- Bleeding, bruising more easily
- Unusual or extreme mood swings
- Dizziness, light-headedness
- Flushing of the face
- Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- Hepatitis (symptoms include loss of appetite, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine)

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation. These side effects are usually very rare:

- Wheezing or difficulty breathing

- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

If you are taking APO-Paracetamol/Codeine 500/30 regularly, you may also need to take laxatives to prevent constipation.

Some people may get other side effects not listed above.

Tell your doctor if you notice anything else that is making you feel unwell.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Paracetamol/Codeine 500/30 looks like

APO-Paracetamol/Codeine 500/30 tablets comes as a white, round, engraved with "PC" on one side and score line on other side.

It comes in boxes of 20 or 50 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains paracetamol 500mg and codeine phosphate Hemihydrate 30 mg as the active ingredient.

It also contains the following inactive ingredients:

- Pregelatinised maize starch
- Stearic acid
- Povidone
- Magnesium stearate

APO-Paracetamol/Codeine does not contain gluten, lactose, sucrose, tartrazine or any azo dyes.

Australian Registration Numbers

APO-Paracetamol/Codeine 500/30:
AUST R 220980

Distributor

Apotex Pty Ltd
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Macquarie Park NSW 2113

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