

Apo-Paracetamol/Codeine 500/30

Contains the active ingredients, Paracetamol and Codeine phosphate

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

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about Apo-Paracetamol/Codeine 500/30.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What Apo-Paracetamol/ Codeine 500/30 is used for

The name of your medicine is Apo-Paracetamol/ Codeine 500/30. It contains the active ingredients, paracetamol and codeine phosphate.

It is used for the relief of moderate to severe pain when milder painkillers are not effective.

How it works

Paracetamol belongs to a group of medicines called analgesics (painkillers). Analgesics are used to block pain. It is also antipyretic which means that it helps reduce your body temperature if you have a fever.

Codeine phosphate also belongs to the group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

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

Your doctor may have prescribed it for another reason.

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

Use in children

This medicine is not suitable for use in children under 7 years of age.

Before you take Apo-Paracetamol/ Codeine 500/30

When you must not take it

Do not take this medicine if you are intolerant or hypersensitive to or have had an allergic reaction to:

- **paracetamol**
- **codeine**
- **morphine**
- **oxycodone**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if you have problems breathing due to asthma, or lung disease such as bronchitis or emphysema.

Do not take this medicine if you are suffering from diarrhoea caused by poisoning or antibiotics.

Do not take this medicine if you regularly drink excessive amounts of alcohol.

The active ingredients of Apo-Paracetamol/Codeine 500/30 pass into breast milk, so it is not recommended for nursing mothers. If you have any concerns you should discuss this with your doctor or pharmacist.

Do not give Apo-Paracetamol/Codeine 500/30 to children under the age of 7 years.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- liver disease or hepatitis, or you are taking other medicines which affect the liver
- kidney disease or difficulty urinating
- inflammatory bowel disease or other gastrointestinal problems
- lung disease or problems breathing
- convulsions or epilepsy
- CNS depression (decreased alertness or decreased consciousness due to any cause)
- Addison's disease (low activity of the adrenal gland)
- an underactive thyroid gland
- recent head injury or brain tumour or increased pressure within the head (intracranial pressure)
- recent gastrointestinal tract or urinary tract surgery
- prostate problems

- heavy alcohol or drug use.

3. You plan to become pregnant or breast-feed.

Like all medicines, Apo-Paracetamol/Codeine 500/30 should not be used during pregnancy without first consulting your doctor.

It is also not recommended for nursing mothers as it passes into breast milk. If this is taken by nursing mothers it may make them drowsy and not as able to look after their babies, and it may also make the babies very sleepy and unable to feed or breathe properly. If this happens you should seek medical advice immediately.

4. You are elderly

Elderly patients are more likely to have less effective kidneys or liver. This may increase the risk of side effects. The codeine in these tablets may also make you feel drowsy or weak.

You should discuss how many tablets to take with your doctor or pharmacist.

5. You are about to have an operation involving a general anaesthetic.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take these tablets with other medicines containing paracetamol or codeine, unless your doctor says you can.

Some medicines and Apo-Paracetamol/Codeine 500/30 may interfere with each other.

These include:

- barbiturates
- medication for epilepsy
- salicylates or NSAIDs, medicines used for pain relief and arthritis
- medicines to help you sleep, or relieve anxiety
- monoamine oxidase inhibitors (MAOI) (for treating depression or Parkinson's Disease) taken within the last 10 days
- medicines to reduce blood pressure
- medicines to treat diarrhoea
- metoclopramide, used to treat nausea and vomiting

- medicines used during operations (anaesthetics, muscle relaxants)
- medicines used to prevent blood clots (anticoagulants)
- chloramphenicol or rifampicin, used for treating bacterial infections
- zidovudine, used for treating viral infections
- cholestyramine, used for lowering cholesterol or treating certain types of diarrhoea
- other strong painkillers called opioids
- medicines called anticholinergics, used for stomach problems (ulcers, cramps, diarrhoea)

These medicines may be affected by Apo-Paracetamol/Codeine 500/30 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking Apo-Paracetamol/Codeine 500/30.

Other interactions not listed above may also occur.

Drinking alcohol with this medicine may increase the toxic effects of alcohol or the side effects of Apo-Paracetamol/Codeine 500/30, and should be avoided.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The recommended doses for Apo-Paracetamol/Codeine 500/30 tablets are:

Adults and children over 12 years:

1 to 2 tablets every four hours as necessary.

Do not take more than eight tablets in one day.

Children 7 to 12 years:

Half a tablet every four hours as necessary.

Children must not take more than three tablets in one day.

Apo-Paracetamol/Codeine 500/30 is not suitable for children under 7 years of age.

How to take it

Swallow the tablet with water. If the dose is half a tablet, there is a break line on the tablet to help you divide it.

When to take it

It does not matter if you take it before, with or after food.

How long to take it for

Adults: Take Apo-Paracetamol/ Codeine 500/30 for no longer than a few days at a time unless your doctor advises otherwise.

Children 7- 12 years: Do not take for longer than 48 hours at a time unless your doctor advises otherwise.

If pain persists, see your 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 doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have 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.

If you take too much Apo-Paracetamol/Codeine 500/30, you may have the following symptoms: weakness, dizziness, lethargy, nausea, vomiting, sweating, mental confusion and low blood pressure.

While you are taking Apo-Paracetamol/ Codeine 500/30

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Apo-Paracetamol/ Codeine 500/30.

Tell your doctor immediately if you become pregnant.

If you are about to have any medical tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Tell your doctor if you feel that this product is not helping your condition.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Do not take any other medicines while you are taking these products without first telling your doctor or pharmacist.

Do not drive or operate machinery until you know how Apo-Paracetamol/Codeine 500/30 affects you.

These tablets may cause dizziness or drowsiness in some people and affect their alertness.

Things to be careful of

Be careful drinking alcohol while taking Apo-Paracetamol / Codeine 500/30.

If you drink alcohol, it could make any unwanted side effects worse. Your doctor or pharmacist may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking these tablets.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness, and dizziness, which may affect driving or operating dangerous machinery.

Make sure you know how you react to Apo-Paracetamol / Codeine 500/30 before you drive a car, operate machinery, or do anything else that could be dangerous.

Children may also be affected so they should be supervised if they are riding bikes or doing other potentially hazardous activities.

Apo-Paracetamol /Codeine 500/30 may be habit forming if used for extended periods of time.

Side effects of Apo-Paracetamol/ Codeine 500/30

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea (feeling sick)
- constipation
- dizziness
- drowsiness
- lethargy

- vomiting (being sick)
- heartburn
- sweating
- mild skin rashes

The above list includes the more common side effects. Mostly, these are mild.

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

- Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal
- Changes in your blood
- Difficulty in urinating (passing water)
- Itchy, raised or red skin rash
- Feeling depressed or troubled
- Feeling excessively elated
- Severe pains in the upper stomach

These may be serious side effects. You may need medical attention.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Symptoms of an allergic reaction, e.g. shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.
- Problems breathing which are not due to allergy

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

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

After taking this medicine

Storage

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

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30 degrees 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 it 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Paracetamol/Codeine 500/30 looks like

Apo-Paracetamol/Codeine 500/30 tablets:

White bevelled edge capsule-shaped tablets, plain on one face with a single break bar on the other side.

Blister packs of 20 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- Wheat starch (contains gluten)
- microcrystalline cellulose
- purified talc
- magnesium stearate
- gelatin.

This medicine is lactose-free, sucrose-free, tartrazine-free and other azo dyes-free.

Australian Registration Numbers

Apo-Paracetamol/Codeine 500/30 tablets

Blister packs

AUST R 153124

Sponsor

Sigma Pharmaceuticals (Australia) Pty Ltd

96 Merrindale Drive

Croydon Victoria 3136

AUSTRALIA

Distributor

Apotex Pty Ltd

ABN 52 096 916 418

66 Waterloo Road

North Ryde, NSW 2113

Australia.

Apotex Pty Ltd is the licensee of the registered trade marks AX logo, APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was prepared in:

May 2009.