

APOHEALTH Paracetamol PLUS Codeine Tablets

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 APOHEALTH Paracetamol PLUS Codeine Tablets. 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APOHEALTH Paracetamol PLUS Codeine Tablets. It contains the active ingredient Paracetamol and Codeine.

This medicine works to:

- Temporarily relieve strong pain including migraine headache, toothache, period pain, minor arthritic pain, and aches and pains associated with cold and flu.
- Reduce fever.

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

How it works

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Codeine phosphate is an opioid pain reliever.

This medicine may be addictive if taken for more than a few days at a time. It is only available from your pharmacist.

Use in children

This medicine should not be used in children under 7 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - Acute breathing difficulties such as bronchitis, unstable asthma or emphysema
 - Chronic constipation
 - Diarrhoea caused by antibiotics or poisoning.

- **You regularly drink large quantities of alcohol.**
- **You are in labour, especially if the baby is premature.**

This medicine may produce withdrawal effects in the newborn baby.

- **You are hypersensitive to, or have had an allergic reaction to, paracetamol, codeine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

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

Before you start to take it

Before you start taking this medicine, tell your doctor or pharmacist 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 or kidney disease
 - difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions
 - history of drug or alcohol dependence
 - recent surgery on the stomach or intestines
 - head injury
 - enlarged prostate
 - low blood pressure
 - underactive thyroid.
3. **You are currently pregnant or you plan to become pregnant.**

Codeine may affect your developing baby. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.
4. **You are currently breastfeeding or you plan to breastfeed.**

A small amount of codeine passes into the breast milk. It may cause breathing problems in newborn infants.

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

5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Do not take with other medicines containing paracetamol.

It is important to check the labels of all other medicines you are taking to make sure they do not contain paracetamol. Taking too much paracetamol may cause serious liver damage.

Some medicines may interact with paracetamol and codeine. These include:

- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives
- medicines used to relieve stomach cramps and spasms
- medicines used to prevent travel sickness
- medicines used to treat Parkinson's disease
- medicines used to treat high blood pressure
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- monoamine oxidase inhibitors, medicines used to treat depression, if taken within the last 14 days
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- other opioids, used to treat pain or suppress coughs
- alcohol.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with paracetamol or codeine.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow carefully all directions for use written on the medicine's label.

Do not take more than the recommended dose on the label or for a longer period of time.

If you do not understand the instructions on the label, ask your pharmacist or doctor for help.

How to much to take

Adults and children over 12 years:

One to two tablets to be taken every four to six hours, when required, up to four times a day. DO NOT exceed 8 tablets in 24 hours.

Children 7 to 12 years:

Half to one tablet to be taken every four to six hours when required up to four times daily. DO NOT exceed 4 tablets in 24 hours. Do not take with other products containing paracetamol unless advised to do so by a doctor or pharmacist.

How to take it

Swallow tablets whole with a glass of water.

How long to take it for

Adults:

Only take this medicine for a few days at a time unless your doctor tells you to take it for longer.

Children and adolescents aged 12 - 17:

Only take the medicine for 48 hours unless your doctor tells you to take it for longer.

If symptoms persist, worsen or new symptoms develop, talk to your pharmacist.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

Taking too much paracetamol can lead to delayed, serious liver damage. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Only take the medicine as recommended on the label.

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not take this medicine with other medicines containing paracetamol unless your doctor or pharmacist tells you to.

Adults:

Do not take for more than a few days at a time unless your doctor or pharmacist tells you to.

Children and adolescents:

Do not take for longer than 48 hours unless your doctor or pharmacist tells you to.

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

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.

Things to be careful of

Do not take high doses the medicine for long periods of time unless your doctor tells you to. Codeine may be habit-forming and too much paracetamol may cause delayed, serious liver damage.

Only drink small quantities of alcohol (beer, wine or spirits) while taking paracetamol. Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness in some people. If this happens, do not drive or use or operate machinery.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APOHEALTH Paracetamol PLUS Codeine Tablets or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

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

- Nausea or dyspepsia
- Vomiting
- Drowsiness
- Dizziness
- Constipation.

The above list includes the more common side effects of your medicines. They are usually mild.

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:

- Unusual or extreme mood swings
- Flushing of the face
- Fast heart beat.

Serious side effects are rare for low doses of this medicine and when used for a short period of time.

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:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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

Tell your pharmacist or doctor if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

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 30°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 or pharmacist 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 APOHEALTH Paracetamol PLUS Codeine Tablets looks like

Paracetamol 500 mg and Codeine Phosphate 10 mg:

White capsule shaped biconvex uncoated tablets.

The product is presented in blister packs of 20 or 40 tablets.

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

Ingredients

Each tablet contains 500 mg of paracetamol and 10 mg of codeine phosphate as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Povidone
- Pre-gelatinised maize starch
- Croscarmellose sodium
- Magnesium stearate
- Maize starch
- Crospovidone and
- Stearic acid

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

Australian Registration Numbers

APOHEALTH Paracetamol PLUS Codeine Tablets (blister pack): AUST R 229518

Sponsor

Apotex Pty Ltd

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