

APOHEALTH Paracetamol PLUS Codeine 15 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 15 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 15 tablets. It contains the active ingredients paracetamol and codeine.

It is used to relieve moderate to severe pain.

Your doctor or pharmacist may have given you this medicine for another use. If you require further information, ask your doctor or pharmacist.

How it works

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.

This medicine may be addictive if taken for more than a few days at a time.

Use in children

This medicine should not be used in children under 12 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- 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.

- Do not take this medicine if you are breastfeeding.
- 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.

Before you start to take it

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

1. You have allergies to:
 - any ingredients listed under at the end of this leaflet
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - lung disease
 - kidney disease
 - liver disease
3. You drink large quantities of alcohol.
4. You are currently pregnant or you plan to become pregnant.
5. You are currently breastfeeding or you plan to breastfeed.

Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
6. 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.

Some medicines may interact with Paracetamol and Codeine. These include:

- medicines causing sleepiness
- tranquillisers (medicines for anxiety and nerves)
- medicines which thin the blood
- medicines to treat epilepsy.

If you are taking any of these you may need a different dose or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

If you have not told your pharmacist or doctor about any of these things, tell him/her before you take this medicine.

How to take this medicine

The label on your pack will tell you how to take your medicine and how often. If you are unsure about the directions ask your doctor or pharmacist.

How much to take and when to take it

The usual dose of this medicine is:

Adults: 2 tablets.

This dosage may be repeated in 4-6 hours if necessary. You should not take more than 8 tablets in a 24 hour period.

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

If the medicine is not adequately controlling your pain, do not increase the dose. Please see your doctor or pharmacist.

This medicine is not recommended for children under 12 years.

How to take it

Swallow tablets whole with a little water or other liquid.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

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.

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 this medicine exactly as your pharmacist or doctor has told you to.

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

Tell your doctor or pharmacist if you become pregnant while taking this medicine.

Things you must not do

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.

- Stop taking your medicine, or change the dosage, without first checking with your doctor or pharmacist.

Things to be careful of

This medicine 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.

This medicine may be habit forming if taken in high doses for extended periods of time. Please ask your doctor or pharmacist if you are concerned about this.

About 8% of people are poor metabolisers of codeine. This may not work as well if you are one of those people.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine 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.

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

- nausea
- vomiting
- stomach pain
- constipation
If you are taking this medicine regularly, you may also need to take laxatives to prevent constipation.
- dizziness
- drowsiness
Be careful driving or operating machinery until you know how this medicine affects you.
- skin rashes

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

If you believe this medicine is not working well for you, do not increase the dose. Please see your pharmacist or doctor.

Allergic reactions

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

Symptoms of an allergic reaction may include some or all of the following:

- 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
- hay fever-like symptoms.

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.

This is not all the information that is available on this medicine. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Product description

What APOHEALTH Paracetamol PLUS Codeine 15 tablets looks like

White to off white capsule shaped uncoated tablets, plain on one side and breakline on the other side.

Available in packs of 20 and 40 tablets.

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

Ingredients

Each tablet contains 500 mg of Paracetamol and 15 mg of Codeine as the active ingredient.

It also contains the following inactive ingredients:

- Starch - Potato
- Lactose
- Povidone
- Docusate sodium
- Silica - colloidal anhydrous
- Magnesium stearate.

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

Australian Registration Numbers

APOHEALTH Paracetamol PLUS Codeine 15 tablets (blister pack): AUST R 229524.

Sponsor

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