

APOHEALTH Cold Relief Tablets

Contains the active ingredients paracetamol and chlorpheniramine maleate

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 Cold Relief 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 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 Cold Relief Tablets. It contains the active ingredients paracetamol and chlorpheniramine maleate.

It is used to provide temporary relief from the following symptoms of colds & flu including:

- Headache
- Sneezing
- Body aches & pains
- Runny nose
- Watery & itching eyes
- Fever.

Your doctor or pharmacist may recommend this medication for another use. If you want more information ask your doctor or pharmacist.

How it works

Paracetamol

Paracetamol is an analgesic and antipyretic. It relieves the elevated body temperature, headache and joint and muscle pain associated with the common cold and influenza.

Chlorpheniramine maleate

Chlorpheniramine maleate is an antihistamine. It helps to control sneezing and relieve itchy and watery eyes. The efficacy of chlorpheniramine in this product is due to its anticholinergic effect.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under 12 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 medical conditions:**
 - Glaucoma (high pressure in the eyes)
 - Prostate problems
 - Bladder problems
 - Stomach or duodenal ulcer or other stomach problems.
- **You are taking any other product containing paracetamol.**
- **You are pregnant.**

Paracetamol and chlorpheniramine maleate may affect your developing baby if you take it during pregnancy. Tell your doctor if you are pregnant or plan to become pregnant. Your doctor or pharmacist can discuss with you the risks and benefits involved.
- **You are breastfeeding.**

Paracetamol and chlorpheniramine maleate may pass into human breast milk. Tell your doctor if you are breastfeeding. Your doctor or pharmacist can discuss with you the risks and benefits involved.
- **You are hypersensitive to, or have had an allergic reaction to paracetamol, chlorpheniramine maleate, any other antihistamine or any other 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. dizziness, nausea or headache.

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 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.

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:
 - you have liver or kidney problems
 - you are having breathing problems
 - you are a heavy drinker
 - you have epilepsy.
3. You are planning to have surgery or an anaesthetic.
4. You are currently receiving or are planning to receive dental treatment.
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.

Some medicines may interact with APOHEALTH Cold Relief Tablets. These include:

- anticoagulants (medicines that thin the blood such as warfarin)
- antidepressants
- medicines containing metoclopramide or propantheline
- medicines for treating epilepsy or fits
- sleeping tablets
- alcohol
- chloramphenicol (an antibiotic).

These medicines may be affected by APOHEALTH Cold Relief Tablets 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 have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you use APOHEALTH Cold Relief Tablets.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Adults and Children over 12 years:

Take 2 tablets every 4 to 6 hours when necessary (maximum 8 tablets in 24 hours. Do not exceed 8 tablets in 24 hours.

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor or pharmacist.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

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

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.

Symptoms of an overdose may include vomiting, stomach pain, hallucination and seizures.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine

- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

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

This medicine is for minor and temporary ailments and should be used strictly as directed. Prolonged use without medical supervision could be harmful.

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

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

This medication may cause drowsiness and/or dizziness in some people. If affected do not drive a vehicle, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness and dizziness may be worse.

Possible side effects

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

Do not be alarmed by the following list 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 if you notice any of the following:

- drowsiness
- dizziness
- allergic reactions
- skin rashes
- nausea
- dry mouth
- vomiting
- constipation or diarrhoea.

If you are 60 years and over you may have an increased chance of getting side effects. Dizziness, drowsiness and a drop in blood pressure causing light-headedness are more likely to occur in elderly patients.

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

Other side effects not listed above may also occur in some people.

Allergic reactions

If you think you are having an allergic reaction to APOHEALTH Cold Relief Tablets, 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 medicines 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 Cold Relief Tablets looks like

APOHEALTH Cold Relief Tablets is an oval shaped white, film-coated tablet with a break bar on one side.

Available in a blister pack containing 24 tablets.

Ingredients

Each tablet contains 500 mg of Paracetamol & 2 mg of Chlorpheniramine maleate as active ingredients.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Silica colloidal
- Magnesium stearate
- Starch-maize
- Povidone
- Sodium starch glycollate
- Opadry 04F58804 White.

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

The Australian Registration Number

APOHEALTH Cold Relief Paracetamol 500 mg & Chlorpheniramine maleate 2 mg Tablets (Blister pack): 254172

Sponsor

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AUSTRALIA

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