

# APOHEALTH Paracetamol Plus Codeine and Calmative Tablets

*Contains the active ingredients paracetamol, codeine phosphate and doxylamine succinate*

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## Consumer Medicine Information

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

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### What is in this leaflet

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#### Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOHEALTH Paracetamol PLUS Codeine and Calmative 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](http://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.

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### What this medicine is used for

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The name of your medicine is APOHEALTH Paracetamol PLUS Codeine and Calmative Tablets. It contains the active ingredient paracetamol, codeine phosphate & doxylamine succinate.

This medicine is used to provide effective temporary relief from the pain and discomfort associated with:

- neck and back pain
- headache
- tension headache
- toothache
- backache
- migraine headache
- muscle pain
- nerve pain
- arthritis
- rheumatics
- osteoarthritis
- period pain
- symptoms of
  - cold
  - sore throat
  - flu
- trauma
- surgery
- dental procedures
- and other pain where a combined calmative and analgesic action is required.

This medicine also reduces fever.

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

#### *How it works*

Paracetamol is an analgesic with antipyretic action, meaning it also reduces fever.

Doxylamine succinate is an antihistamine with pronounced sedative effects.

Codeine phosphate is an analgesic, and in combination with paracetamol and doxylamine produces greater analgesia than any of these drugs alone and avoids the side effects associated with large doses of codeine.

#### *Use in children*

This medicine should not be used in children under 17 years of age.

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### Before you take this medicine

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#### *When you must not take it*

**Do not take this medicine if:**

- **You have or have had any of the following:**
  - glaucoma (high pressure in the eyes)
  - stomach or duodenal ulcer, or other stomach problems
  - prostate problems
  - bladder problems
  - acute breathing difficulties such as bronchitis, unstable asthma or emphysema
  - chronic constipation
  - diarrhoea caused by antibiotics or poisoning
- **You have alcohol dependence.**
- **You are in labour, especially if the baby is premature.**  
The medicine may produce withdrawal effects in the newborn baby.
- **You are breastfeeding.**  
It passes into the breast milk and there is a possibility that the baby may be affected.
- **You are also taking monoamine oxidase inhibitors, a type of medicine used to treat depression.**
- **You are hypersensitive to, or have had an allergic reaction to, paracetamol, codeine, doxylamine 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 be taking this medicine, talk to your doctor or pharmacist.

### *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:
  - kidney or liver problems
  - epilepsy
  - difficulty breathing
  - wheezing
  - chronic cough
  - asthma
  - other chronic breathing conditions
  - glaucoma
  - urinary retention
  - chronic alcohol consumption
  - a history of drug dependence, alcohol dependence
  - recent surgery on the stomach or intestines
  - head injury
  - prostate problems
  - low blood pressure
  - underactive thyroid
3. You are currently pregnant or you plan to become pregnant.  
Do not take this medicine whilst pregnant until you and your doctor or pharmacist have discussed the risks and benefits involved.
4. 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.
5. You are planning to have surgery.
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.

### *Taking other medicines*

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

Some medicines may interact with paracetamol, codeine and doxylamine.

These include:

- sleeping tablets or sedatives
- medicines to control fits or anti-epileptic drugs e.g. Dilantin or Tegretol
- anti-depressant tablets
- anti-coagulant tablets

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 will advise you.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

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## How to take this medicine

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

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

### *How much to take*

The usual dose for adults and children over 12 years of age is one to two tablets every 4 to 6 hours, as needed for pain relief.

**Do not take more than 8 tablets in a 24 hour period.**

**Do not give this medicine to a child under 12 years.**

### *How to take it*

Swallow the tablets with a full glass of water.

### *When to take it*

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

### *How long to take it for*

This medicine is for short term use only.

#### **Adults:**

Do not take this medicine for longer than a few days at a time unless advised by a doctor.

#### **Adolescents:**

Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.

If pain persists for more than three days, please see your doctor

### *If you forget to take it*

There is no need to take extra doses if the pain has gone away.

If the pain is still present, take your next dose if required.

### **Do not take a double dose to make up for missed doses.**

This may increase the chance of you experiencing side effects.

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 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.**

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## **While you are taking this medicine**

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### *Things you must do*

Tell your doctor or pharmacist that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breastfeeding or are planning to breastfeed
- 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.**

### **Tell your doctor or pharmacist if:**

- you develop a skin rash or hives while taking this medicine
- you become pregnant while taking this medicine

### *Things you must not do*

#### **Do not:**

- Drink alcohol.
- 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 medicine may cause drowsiness or lightheadedness in some people and affect mental alertness.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you get dizzy

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## **Possible side effects**

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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.

This medicine helps most people with pain, but may have unwanted side effects in a few people.

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 if you notice any of the following:**

- drowsiness
- depression
- dizziness
- feeling sick or stomach pains
- diarrhoea
- loss of appetite, weight loss
- constipation
- skin rashes

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

### *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.

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## Storage and disposal

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### *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.

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## Product description

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*What APOHEALTH Paracetamol PLUS Codeine and Calmative Tablets looks like*

Paracetamol 500mg, Codeine Phosphate 10mg and Doxylamine 5.1mg tablets:

White, capsule shaped, biconvex, bevel edged, uncoated tablets with break line on one side and plain on other side.

It is available in packs of 20 and 40 tablets.

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

### *Ingredients*

Each tablet contains 500mg of paracetamol, 10mg codeine phosphate, 5.1mg doxylamine succinate as the active ingredients.

It also contains the following inactive ingredients:

- Lactose
- Starch-Maize
- Povidone
- Ethanol
- Crospovidone
- Cellulose-microcrystalline, Stearic Acid
- Magnesium Stearate.

### *Australian Registration Numbers*

APOHEALTH Paracetamol PLUS Codeine and Calmative Tablets (blister pack): AUST R 230135

### *Sponsor*

**Apotex Pty Ltd**  
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This leaflet was last updated in January 2015.