

# APOHEALTH Ibuprofen Plus Paracetamol

Active ingredient(s): *Ibuprofen 200 mg and paracetamol 500 mg*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APOHEALTH Ibuprofen Plus Paracetamol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APOHEALTH Ibuprofen Plus Paracetamol.**

### Where to find information in this leaflet:

- [1. Why am I using APOHEALTH Ibuprofen Plus Paracetamol?](#)
- [2. What should I know before I use APOHEALTH Ibuprofen Plus Paracetamol?](#)
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## 1. Why am I using APOHEALTH Ibuprofen Plus Paracetamol?

APOHEALTH Ibuprofen Plus Paracetamol contains the active **ibuprofen and paracetamol**. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Paracetamol works to stop the pain messages from getting through to the brain.

APOHEALTH Ibuprofen Plus Paracetamol is an analgesic (pain reliever). It works to relieve acute (short term) pain and / or inflammation associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, period pain, sore throat, tennis elbow, rheumatic pain and arthritis, and the aches and pains associated with colds and flu.

## 2. What should I know before I use APOHEALTH Ibuprofen Plus Paracetamol?

### Warnings

**Do not use APOHEALTH Ibuprofen Plus Paracetamol if:**

- you are allergic to ibuprofen, paracetamol or any of the ingredients listed at the end of this leaflet.
- you are allergic to any other medicine for pain relief

Some of the symptoms of an allergic reaction may include:

- 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

Always check the ingredients to make sure you can use this medicine.

**Do not use APOHEALTH Ibuprofen Plus Paracetamol if you have the following conditions:**

- liver or kidney disease
- heart problems
- asthma
- a stomach ulcer or duodenal ulcer or if you have had either of these conditions or gastric bleeding or other gastrointestinal diseases in the past
- recently vomited blood or material that looks like coffee grounds
- recently bled from the back passage (rectum), had black sticky bowel motions or bloody diarrhoea

Some of the symptoms of liver problems may include:

- nausea
- feeling tired
- itching of the skin,
- yellow colouring of your skin
- flu-like symptoms
- tenderness in your abdomen

If you develop any of these symptoms or heart problems, talk to your doctor.

**Do not take this medicine if you are taking any other product containing paracetamol, ibuprofen or other NSAIDs or if you are taking any other medicine for pain relief.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** If it has expired or is damaged, return it to your pharmacist for disposal.

**Check with your doctor or pharmacist if you:**

- have allergies to any other medicines, foods, preservatives or dyes
- have, or have had, any other medical conditions:
  - diabetes
  - asthma
  - liver or kidney disease
  - heart problems
- take any medicines for any other condition
- are not sure whether you should start taking APOHEALTH Ibuprofen Plus Paracetamol

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Do not take this medicine if you are pregnant or plan to become pregnant.**

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Small amounts of ibuprofen and paracetamol pass into the breast milk.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with APOHEALTH Ibuprofen Plus Paracetamol and affect how it works. These include:**

- warfarin, a medicine used to prevent blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to lower blood pressure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other nonsteroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- 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
- alcohol
- Flucloxacillin (an antibiotic), due to a serious risk of blood and fluid abnormality (metabolic acidosis)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APOHEALTH Ibuprofen Plus Paracetamol.**

### 4. How do I use APOHEALTH Ibuprofen Plus Paracetamol?

#### How much to take

- Adults under 65 and children from 12 years:
  - Take one tablet every 8 hours with water when necessary
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.
  - Adults: do not take APOHEALTH Ibuprofen Plus Paracetamol for more than 3 days at a time.
  - Adolescents (12 to 17 years): do not take APOHEALTH Ibuprofen Plus Paracetamol for more than 2 days at a time.

**Do not take more than 3 tablets in 24 hours.**

#### When to take APOHEALTH Ibuprofen Plus Paracetamol

- APOHEALTH Ibuprofen Plus Paracetamol should be used when required for pain.
- If your symptoms persist, worsen or new symptoms develop, talk to your pharmacist or doctor.

#### If you use too much APOHEALTH Ibuprofen Plus Paracetamol

If you think that you have used too much APOHEALTH Ibuprofen Plus Paracetamol, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using APOHEALTH Ibuprofen Plus Paracetamol?

#### Things you should do

- **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.

Remind any doctor, dentist or pharmacist you visit that you are using APOHEALTH Ibuprofen Plus Paracetamol.

#### Things you should not do

- Do not take APOHEALTH Ibuprofen Plus Paracetamol for more than 3 days at a time (2 days for adolescents 12 to 17 years) unless your doctor tells you to.
- Do not take more than the recommended dose unless your pharmacist or doctor tells you to.
- Do not take APOHEALTH Ibuprofen Plus Paracetamol to treat any other complaints unless your pharmacist or doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take APOHEALTH Ibuprofen Plus Paracetamol if you are aged 65 years or older.

#### Things to be careful of

- Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems

#### Driving or using machines

Be careful before you drive or use any machines or tools until you know how APOHEALTH Ibuprofen Plus Paracetamol affects you.

#### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

- 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

#### Looking after your medicine

- Keep your medicine in the original pack until it is time to take it.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking APOHEALTH Ibuprofen Plus Paracetamol.**

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

It is rare to get side effects from ibuprofen and paracetamol if taken for a short period of time and in the doses in OTC medicines.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### Less serious/common side effects

This list includes the more common side effects of your medicine. They are usually mild.

Less serious side effects	What to do
<ul style="list-style-type: none"><li>nausea, heartburn, or stomach pain</li><li>loss of appetite</li><li>diarrhoea</li><li>dizziness</li><li>drowsiness</li><li>headache</li><li>nervousness</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

### Serious/rare side effects

This list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of time.

Serious side effects	What to do
<ul style="list-style-type: none"><li>if you get sunburnt more quickly than usual</li></ul>	<b>Tell your doctor as soon as possible</b>

### Very serious/ very rare side effects

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

Very serious side effects	What to do
<ul style="list-style-type: none"><li>fluid retention</li><li>vomiting blood or bleeding from the back passage</li><li>shortness of breath</li><li>wheezing or difficulty breathing</li><li>swelling of the face, lips, tongue or other parts of the body</li><li>rash, itching or hives on the skin</li><li>symptoms of metabolic acidosis which may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting) and loss of appetite</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What APOHEALTH Ibuprofen Plus Paracetamol contains

<b>Active ingredient (main ingredient)</b>	Each APOHEALTH Ibuprofen Plus Paracetamol <b>tablet</b> contains: <ul style="list-style-type: none"><li>200mg of ibuprofen and</li><li>500mg of paracetamol</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>pregelatinised maize starch</li><li>povidone</li><li>crospovidone</li><li>microcrystalline cellulose</li><li>colloidal anhydrous silica</li><li>magnesium stearate</li><li>hypromellose</li><li>purified talc</li><li>titanium dioxide</li><li>Opadry FX silver</li></ul>
<b>Potential allergens</b>	APOHEALTH Ibuprofen Plus Paracetamol does not contain lactose, sucrose, gluten, wheat, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What APOHEALTH Ibuprofen Plus Paracetamol looks like

APOHEALTH Ibuprofen Plus Paracetamol **tablets** are a white to off white, oval shaped biconvex, film-coated pearlescent tablet plain on both sides.

It is available in packs of 12 and 24 tablets.

AUST R 277635

**Who distributes APOHEALTH**

**Ibuprofen Plus Paracetamol**

**Tablets**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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