

APOHEALTH Ibuprofen Plus Codeine Tablets

Contains the active ingredients ibuprofen and codeine

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 Ibuprofen 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 Ibuprofen Plus Codeine Tablets. It contains the active ingredients ibuprofen and codeine.

This medicine relieves inflammation and strong pain associated with:

- migraine headache
- tension headache
- headache
- period pain
- dental pain
- back pain
- neuralgia
- rheumatic pain
- arthritic pain
- muscular pain.

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

How it works

Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, inflammation (swelling, redness, soreness) and fever.

Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

There is evidence that using these types of medicines can lead to dependence.

Use in children

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

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:**
 - vomiting blood or material that looks like coffee grounds
 - bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
 - stomach ulcer
 - chronic constipation or shallow breathing, or severe diarrhoea
 - consume heavy amounts of alcohol regularly
- **You are pregnant, unless advised by your doctor.** NSAIDs should not be taken during pregnancy.
- **You are in the last three months of pregnancy.**

- **You are taking medicines that contain one or more NSAIDs, whether prescribed by your doctor or obtained without prescription.**

Several medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAIDs. If you are not sure if the medicines you are taking contain these ingredients, ask your pharmacist.

- **You are hypersensitive to, or have had an allergic reaction to:**

- ibuprofen, aspirin or other NSAID medicines.

- allergy symptoms may be severe.

- codeine or other opioid analgesics such as morphine or pethidine.

- 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, contact 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:
 - a history of stomach ulcer.
 - liver disease.
 - kidney disease.
 - heart failure.
 - swelling of ankles or feet.
 - asthma, or have suffered in the past from asthma.
 - thyroid problems or low blood pressure.
 - a head injury or intercranial pressure.
 - prostate problems.
 - stomach problems or recent stomach surgery.
3. You are currently pregnant or you plan to become pregnant. This medicine is not recommended for use during pregnancy. Your doctor will decide if you should take this medicine.
4. You are currently breastfeeding or you plan to breastfeed. This medicine is not recommended while you are breastfeeding. If there is a need to consider this medicine while you are breastfeeding, your pharmacist or doctor will discuss the benefits and risks involved.
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

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

- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to stop blood clots or thin the blood.

- medicines that are used to treat high blood pressure eg diuretics (fluid tablets) or heart problems.
- methotrexate a medicine used to treat arthritis and some types of cancer.
- zidovudine a medicine used to treat HIV infection.
- lithium and other medicines used to treat depression or anxiety eg MAOIs (even if taken within the last 14 days).
- medicines used to relieve stomach cramps or spasms.
- medicines used to treat diarrhoea (eg kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting.
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system.
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives.
- quinidine, a medicine used to treat abnormal or irregular heart beat.
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders.
- medicines used to treat diabetes.
- medicines used to treat Parkinson's disease.
- medicines used to prevent travel sickness.
- other opioids to treat pain or suppress cough.

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 this medicine.

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

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 of age:

2 tablets followed by, if necessary, 1 or 2 tablets every 4 hours.

Do not take more than 6 tablets in 24 hours.

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

How to take it

Take this medicine by mouth with fluid. It may also be taken before, or after food.

How long to take it for

You should not take this medicine for more than a few days.

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

If you take too much (overdose)

If you take too much of this medicine you may experience nausea or upset stomach, vomiting and gastric irritation, drowsiness, dizziness or very slow, laboured breathing. You may also experience blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes. Excitability, convulsions and unconsciousness may be experienced in rare cases.

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor 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.

While you are taking this medicine

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 pregnant or are planning to become pregnant
- 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.

Stop taking this medicine and tell your doctor or pharmacist:

- if you become pregnant while taking this medicine.

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

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.
- Take this medicine with any other product containing ibuprofen and or codeine/ other opioid unless your doctor tells you.

- Take for more than a few days at a time unless your doctor tells you to.

Things to be careful of

- Be careful when driving or operating machinery until you know how this medicine affects you.
This medicine may cause dizziness, light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, light-headedness or drowsiness may be worse.
- Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.

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 if you notice any of the following:

- stomach upset including nausea (feeling sick), vomiting.
- heartburn, indigestion.
- diarrhoea, pain in the stomach.
- dizziness, light-headedness, drowsiness.
- constipation.
- cough suppression.
- headache.
- hearing disturbance.

These are the more common side effects of this medicine and are usually mild and short lived.

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:

- vomiting blood or material that looks like coffee grounds.
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- asthma, wheezing, shortness of breath, pain or tightness in the chest.
- sudden or severe itching, skin rash, hives, skin peeling.
- easy bruising.
- shallow breathing.
- fluid retention.

These side effects are rare.

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

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.

It also contains the following inactive ingredients:

- Starch - pregelatinised maize
- Cellulose microcrystalline
- Croscarmellose sodium
- Silica colloidal anhydrous
- Water purified
- Opadry white colouring

This medicine does not contain gluten or preservatives.

Australian Registration Numbers

APOHEALTH Ibuprofen Plus Codeine Tablets (blister pack):
AUST R 227876

Sponsor

Apotex Pty Ltd
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Macquarie Park NSW 2113

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This leaflet was last updated in January 2015.

Product description

What APOHEALTH Ibuprofen Plus Codeine Tablets looks like

Ibuprofen 200mg and Codeine 12.8mg tablets:
White to off-white capsule-shaped, biconvex, film-coated tablet.
Blister packs of 20 or 30 tablets.

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

Ingredients

Each tablet contains 200mg ibuprofen and 12.8mg codeine phosphate as the active ingredients.