

APOHEALTH Ibuprofen Plus Paracetamol

Ibuprofen and paracetamol

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What this medicine is used for

This medicine contains two active ingredients, paracetamol and ibuprofen, that together deliver temporary relief of short-term pain and/or inflammation associated with back pain, dental pain, period pain, migraine headache, cold and flu symptoms, tension headache, muscular pain, headache, sore throat, tennis elbow, rheumatic pain and non-serious arthritic pain.

Paracetamol works to stop the pain messages from getting through to the brain. Paracetamol also acts in the brain to reduce fever.

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.

Your doctor or pharmacist may have given you this medicine for another use.

This medicine is not recommended for children under 12 years of age.

If you want more information, ask your doctor or pharmacist.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing ibuprofen or paracetamol
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines such as aspirin, NSAIDs or other medicines to relieve pain.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face or throat, lips, tongue or other parts of the body
- rash, itching or hives on the skin, runny or stuffy nose when using

aspirin, or other non-steroidal anti-inflammatory drugs or analgesic products.

- stomach ache, fever, chills, nausea, vomiting and/or fainting.

If you are allergic to aspirin or NSAIDs medicines and take this medicine, these symptoms may be severe.

Do not take this medicine if you are also taking any other medicines that contain one or more NSAID medicine, whether prescribed by your doctor or obtained without a 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.

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

Like most medicines of this kind, this medicine is not recommended to be used during pregnancy.

Use of this medicine may cause the baby to have kidney problems leading to a low amount of amniotic fluid inside the uterus and in some cases kidney problems in the newborn

Ask your doctor or pharmacist about taking this medicine if you

are breastfeeding or planning to breast-feed.

Small amounts of Ibuprofen and paracetamol may pass into the breast milk

If you have not told your doctor or pharmacist about any of the above, tell them before start taking this medicine.

Do not take this medicine if you have any of the following conditions:

- asthma, bronchitis, emphysema or other acute breathing difficulties
- bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- if you have 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.
- recent vomiting of blood or material that look like coffee grounds
- you have had bleeding episodes which cannot be explained
- you are using other paracetamol-containing products
- you are severely dehydrated after having vomited, had diarrhoea or not enough to drink
- liver or kidney disease
- heart problems

Do not take this medicine if you regularly drink large quantities of alcohol.

Do not give this medicine to children under 12 years of age.

Do not give this medicine to dehydrated adolescents.

Do not take if you are aged 65 years or older.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

You must tell your doctor or pharmacist if you have allergies to any of the ingredients listed at the end of this leaflet.

Do not take this medicine with other medicines containing paracetamol or ibuprofen, aspirin, salicylates or with any other anti-inflammatory medicines, unless advised to do so by a doctor or pharmacist.

You must tell your doctor if you have ever had any of the following conditions:

- have a severe and extensive skin rash known as DRESS with following reactions such as fever, rash, enlargement of lymph nodes and/or facial swelling, kidney problems, blood disorder, inflammation of the heart, muscle weakness/pain
- diabetes, liver, kidney or heart problems, gastrointestinal or autoimmune problems (where your own immune system mistakenly attacks substances naturally occurring in your body).
- Take any medicines for any other condition
- asthma, or have suffered in the past from asthma.
- you drink large quantities of alcohol
- you have a history or drug or alcohol abuse
- have recently had major surgery
- suffer from hayfever, nasal polyps or have chronic respiratory disorders. These may increase the risk of an allergic reaction occurring
- previous history of ulcers
- have a metabolic disorder
- have a blood platelet disorder

If you currently have any of the above conditions, you should not take this medicine.

Tell your doctor or pharmacist if you have an infection.

This medicine may hide signs of infections such as fever and pain.

It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications.

This has been observed in patients with serious lung infections (also called pneumonia) caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

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.

Taking other medicines

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

Some medicines and this one may interfere with each other. These include:

- other paracetamol containing products, analgesics, other medicines for pain relief
- antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs)
- aspirin, salicylates or other NSAID medicines
- warfarin or other medicines used to stop blood clots or thin the blood
- zidovudine a medicine used to treat HIV infection
- medicines used to treat diabetes
- lithium and other medicines used to treat depression or anxiety e.g. MAOIs (even if taken within the last 14 days)
- medicines used to lower blood pressure such as diuretics, ACE

- inhibitors, beta-receptor blockers and angiotensin-II antagonists
- medicines that contain probenecid or sulfinpyrazone
- digoxin, a medicine used to treat irregular heart rhythms
- medicines to treat epilepsy or fits (seizures)
- metoclopramide, a medicine used to control nausea and vomiting
- propantheline, a drug used to treat stomach ulcers
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to relieve stomach cramps or spasms
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- probenecid, a medicine used to treat high uric acid levels in blood associated with gout
- cholestyramine, a medicine used to reduce blood cholesterol
- ciclosporin or tacrolimus, medicines used to treat immune system conditions
- alcohol
- methotrexate, a medicine used to treat arthritis and some types of cancer
- diuretics, also call fluid tablets
- medicines used to treat high failure.
- CYP2C9 inhibitors such as voriconazole and fluconazole
- Uricosurics which may delay the excretion of ibuprofen

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Your doctor and pharmacist have more information on medicines to be

careful with or avoid while taking this medicine.

How to take this medicine

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

How much to take

Adults under 65 and children over 12 years: 1 tablet three times a day when necessary (every 8 hours).

You should not take more than 3 tablets in 24 hours.

Do not take more than the recommended dose.

Not recommended for adults 65 years of age and over or children under 12 years of age.

How to take it

Swallow the tablets with little water or other liquid

It is recommended that patients with sensitive stomachs take this medicine with food.

If taken shortly after eating it may take a little longer for this medicine to work. Do not take more this medicine than recommended until it is time to take the next dose.

How long to take it

Adults: Do not take this medicine for longer than 3 days at a time unless advised to by a doctor.

Adolescents 12 – 17 years: Do not take this medicine for longer than 2 days at a time, unless advised to by a doctor.

Do not take more than 3 tablets in a 24 hour period.

Take the lowest dose that helps with your pain for the shortest time necessary to relieve your symptoms.

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen.

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

Prolonged use of any type of pain relievers for headaches can make it worse. If this is experienced or suspected, medical advice should be obtained or discontinued.

The habit of taking medicines for pain relief particularly in combination with other pain-relievers may lead to permanent kidney problems including kidney failure therefore it should be avoided.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention because of the risk of delayed, serious liver damage with an overdose of paracetamol.

If you take too many tablets you may feel nauseous or have an upset stomach, experience vomiting and gastric irritation, feel light headed, dizzy or drowsy. Excitability, convulsions and unconsciousness may be experienced in rare cases.

While you are using this medicine

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop a skin rash, mucosal wounds or any other sign of allergy while you are using this medicine, stop taking the product and tell your doctor or pharmacist immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe.

Do not give this medicine to anyone else even if they have the same symptoms as you.

Adults: Do not take this medicine for longer than 3 days at a time unless advised to by a doctor.

Adolescents 12 – 17 years: Do not take this medicine for longer than 2

days at a time, unless advised to by a doctor.

Do not give this medicine to children under 12 years of age.

Do not take if you are aged 65 years or older.

Do not take more than the recommended dose unless your doctor tells you to.

Do not take this medicine if you are taking other medicines that contain aspirin, paracetamol, ibuprofen, salicylates or other anti-inflammatory medicines or other medicines for pain relief.

Things to be careful of

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

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.

Avoid drinking 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.

Side effects

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

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea
- stomach pain
- diarrhoea
- loss of appetite
- heartburn
- dizziness
- light-headedness
- drowsiness
- nervousness

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.

Tell your doctor as soon as possible if you get sunburnt more quickly than usual

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.

Tell your doctor as soon as possible if you notice any of the following:

- shortness of breath
- vomiting blood or bleeding from the back passage
- 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
- fluid retention.

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.

Storage and Disposal

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or blister pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car, especially on hot days.

Heat and dampness can destroy some medicines.

Keep it 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

- povidone
- crospovidone
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- purified talc
- titanium dioxide
- Opadry FX silver

This medicine does not contain lactose, sucrose, gluten, wheat, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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Product description

What it looks like

APOHEALTH Ibuprofen Plus Paracetamol Tablets come as 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

Ingredients

Each tablet contains 500 mg of paracetamol and 200 mg of ibuprofen as the active ingredients.

This medicine also contains the following:

- pregelatinised maize starch