

IBUPANE®

Active ingredient(s): *paracetamol and ibuprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IBUPANE. **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 IBUPANE.**

Where to find information in this leaflet:

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1. Why am I using IBUPANE?

IBUPANE contains two active ingredients paracetamol and ibuprofen. IBUPANE belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). This group of medicines work by relieving pain, inflammation (swelling, redness, soreness) and fever. Paracetamol works to stop the pain messages from getting through to the brain and also acts in the brain to reduce fever.

IBUPANE is used for temporary relief of 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. Reduces fever.

2. What should I know before I use IBUPANE?

Warnings

Do not use IBUPANE if you are allergic to paracetamol, ibuprofen, aspirin, other NSAIDs or any of the ingredients listed at the end of this leaflet.

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
- Stomach ache, fever, chills, nausea and vomiting, fainting

If you are allergic to aspirin or NSAIDs medicines and take IBUPANE tablets these symptoms may be severe.

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

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

- Heart problems
- Liver or kidney disease

- 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
- If you have had bleeding episodes which cannot be explained
- Recent vomiting of blood or material that look like coffee grounds
- 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 IBUPANE tablets if you are also taking any other medicines that contain one or more NSAID medicine or if you are taking any other medicine for pain relief, 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.

Do not give IBUPANE tablets to children aged under 12 years.

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

Do not give IBUPANE tablets to dehydrated adolescents.

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

Check with your doctor or pharmacist if you:

- have allergies to any ingredients listed under "Product Details" at the end of this leaflet.
- have severe skin reactions such as 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
- suffer from hayfever, nasal polyps or have chronic respiratory disorders. These may increase the risk of an allergic reaction occurring.
- Have, or have had, any of these conditions:
 - Liver, kidney or heart problems
 - Asthma, or have suffered in the past from asthma.
 - You drink large quantities of alcohol
 - You have a history of drug or alcohol abuse
 - Recent surgery on the stomach or intestines
 - Previous history of ulcers
 - Diabetes
 - Autoimmune problems (where your own immune system mistakenly attacks substances naturally occurring in your body)

- Have recently had major surgery
- have a metabolic disorder
- have a blood platelet disorder

If you currently have any of these conditions you should not take this medicine.

- take any medicines for any other condition
- are breastfeeding or planning to breast-feed.
- are over 65 years of age and have kidney or respiratory problems
- are not sure whether you should start taking IBUPANE.

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.

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

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

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

Use of IBUPANE 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.

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 IBUPANE and affect how it works. These include:

- other paracetamol containing products, analgesics, other medicines for pain relief
- Aspirin, salicylates or other NSAID medicines.
- Warfarin or other medicines used to stop blood clots or thin the blood.
- antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs)
- Zidovudine a medicine used to treat HIV infection.
- Lithium and other medicines used to treat depression or anxiety e.g. MAOIs (even if taken within the last 14 days).
- Medicines to treat epilepsy or fits
- 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
- Corticosteroids such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- Probenecid, as drug used to treat high uric acid levels in blood associated with gout
- Colestyramine, as drug used to reduce blood cholesterol
- Methotrexate, a medicine used to treat arthritis and some types of cancer

- Diuretics, also called fluid tablets
- Alcohol
- Medicines used to treat high blood pressure or heart failure or other heart conditions
- Medicines used to treat diabetes. These medicines may be affected by IBUPANE tablets or affect how well IBUPANE tablets work.

IBUPANE may hide signs of infections such as fever and pain. It is therefore possible that IBUPANE 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.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IBUPANE.

4. How do I use IBUPANE?

How much to take

- Adults under 65 and children over 12 years:
 - 1 tablet three times a day when necessary (every 8 hours).
- Follow the instructions provided and use IBUPANE until your doctor tells you to stop.
- Do not exceed the recommended dosage.
 - 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.**

As with other NSAIDs, excessive or prolonged use of ibuprofen may increase the risk of heart attack, stroke or liver damage.

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

How to take IBUPANE

- Swallow tablet whole with a little water or other liquid.
- The directions given to you by your pharmacist or doctor may be different from the information in this leaflet. If you are unsure what dose to take, ask your pharmacist or doctor.

If you use too much IBUPANE

If you think that you have used too much IBUPANE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

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

Keep telephone numbers of these places handy.

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

5. What should I know while using IBUPANE?

Things you should do

Take IBUPANE tablets exactly as your pharmacist or doctor has told you to.

If IBUPANE tablets are not adequately controlling your pain, do not increase the dose. Please talk to your doctor or pharmacist if your symptoms do not improve. Your doctor or pharmacist will assess your condition and decide if you should continue to take the medicine.

Tell your doctor or pharmacist if you become pregnant while taking IBUPANE tablets.

Remind any doctor, dentist or pharmacist you visit that you are using IBUPANE.

Things you should not do

- **Do not give this medicine to children under 12 years of age or for adults 65 years of age and over.**
- Do not take this medicine for longer than 3 days at a time (2 days for adolescents 12 to 17 years) unless advised to by a doctor.
- Do not take more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not use this medicine to treat any other complaint unless your doctor or pharmacist tells you to.
- Do not give your medicine to anyone else even if they have the same symptoms as you.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IBUPANE affects you.

IBUPANE 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.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Avoid drinking alcohol. Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Looking after your medicine

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

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 doctor or pharmacist as soon as possible if you do not feel well while taking IBUPANE tablets.

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 about side effects.

Less serious 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"> • Nausea • Vomiting • Stomach pain • Loss of appetite • Diarrhoea • Heartburn, indigestion • Dizziness • Light-headedness • Drowsiness • Headache • Nervousness • Sweating 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

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">• Skin rashes• Yellowing of the skin and eyes also called jaundice• Painful red areas with blisters and peeling layers of skin which may be accompanied by fever and/or chills• Flushing of the face• Fast heartbeat• If you get sunburnt more quickly than usual.	Tell your doctor as soon as possible.

Very serious 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.

Serious side effects	What to do
<ul style="list-style-type: none">• Fluid retention• 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.• Swelling of other parts of the body• Asthma, wheezing, shortness of breath, pain or tightness in the chest• Sudden or severe itching, skin rash, hives, skin peeling	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What IBUPANE contains

Active ingredient (main ingredient)	Each IBUPANE tablet contains:
	<ul style="list-style-type: none">• Paracetamol 500 mg• Ibuprofen 200 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Pregelatinised maize starch• Povidone• Crospovidone• Microcrystalline cellulose• Colloidal anhydrous silica• Magnesium stearate• Hypromellose• Purified talc• Titanium dioxide• OPADRY fx special effects film coating system 63F97546 SILVER (ARTG PI No: 106945)

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

What IBUPANE looks like

IBUPANE is white to off white, oval shaped biconvex, film-coated pearlescent tablet plain on both sides (AUST R 267396).

It is available in packs of 12 and 24 tablets.

Who distributes IBUPANE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in September 2023.

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