

# IBUDEINE Tablets

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using IBUDEINE?

Ibuprofen contains the active ingredients Ibuprofen and Codeine phosphate. Ibuprofen is used to provide temporary relief of acute moderate pain and inflammation.

For more information, see Section [1. Why am I using Ibuprofen?](#) in the full CMI.

### 2. What should I know before I use IBUDEINE?

Do not use if you have ever had an allergic reaction to Ibuprofen or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant.**

You may develop addiction, dependence and tolerance. For more information, see Section [2. What should I know before I use Ibuprofen?](#) in the full CMI.

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

Some medicines may interfere with Ibuprofen and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use IBUDEINE?

- The usual dose of Ibuprofen is 2 tablets then, if necessary 1 or 2 tablets every 4 to 6 hours.

More instructions can be found in Section [4. How do I use Ibuprofen?](#) in the full CMI.

### 5. What should I know while using IBUDEINE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Ibuprofen.</li><li>• Talk to your doctor about pain control if Ibuprofen is not helping.</li><li>• Tell your doctor if you become pregnant while taking Ibuprofen.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take more than 6 tablets in 24 hours.</li><li>• Do not give Ibuprofen to children under the age of 12 years</li><li>• Do not take Ibuprofen for more than three days at a time</li></ul>
<b>Driving or using machines</b>	Be careful before you drive or use any machines or tools until you know how Ibuprofen affects you. Ibuprofen may cause dizziness light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not drink alcohol while taking Ibuprofen.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep the tablets in a cool dry place where the temperature stays below 30°C.</li></ul>

For more information, see Section [5. What should I know while using Ibuprofen?](#) in the full CMI.

### 6. Are there any side effects?

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following side effects; asthma, wheezing or shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash, fainting. These may be the sign of an allergic reaction.

Speak to your doctor if you have any of the following common side effects and they worry you; nausea or vomiting, constipation, or dizziness, light-headedness, drowsiness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

**WARNING:**

**Limitations of use**

Ibuprofen should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

**Hazardous and harmful use**

Ibuprofen poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

**Life threatening respiratory depression**

Ibuprofen **can** cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time, but the risk is higher when first starting Ibuprofen and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

**Use of other medicines while taking Ibuprofen**

**Using Ibuprofen with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis oil and alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death.**

Your doctor will minimise the dose and duration of use and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Ibuprofen.

# Ibudeine Tablets

**Active ingredients:** Ibuprofen 200 mg and Codeine phosphate hemihydrate 12.8 mg

## Consumer Medicine Information (CMI)

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

### Where to find information in this leaflet:

- [1. Why am I using Ibudeine?](#)
- [2. What should I know before I use Ibudeine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ibudeine?](#)
- [5. What should I know while using Ibudeine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using IBUDEINE?

**Ibudeine contains the active ingredients Ibuprofen and Codeine phosphate.** Ibuprofen belongs to a family of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). These medicines work by relieving pain and/ or inflammation (swelling, redness, soreness) and fever. Codeine is an opioid analgesic that works in the brain and spinal cord to relieve pain.

**Ibudeine is used to provide temporary relief of acute moderate pain and inflammation in patients over the age of 12 years.**

After taking codeine, the body changes codeine into the active morphine by a special liver enzyme. However, about 8% of people may experience less pain relief compared to others, as their bodies do not change codeine to morphine as well as others.

## 2. What should I know before I use IBUDEINE?

### Warnings

Do not give Ibudeine to children under the age of 12 years.

### Do not use Ibudeine if:

- you are allergic to ibuprofen, codeine, other opioids, or any medicine containing ibuprofen, aspirin or other NSAIDs or any of the ingredients listed at the end of this leaflet.

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

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

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting
- if you are allergic to aspirin or NSAIDs and take Ibudeine these symptoms may be severe
- you are in the last three months of pregnancy or are breast-feeding
- you are vomiting blood or material that looks like coffee grounds
- you are bleeding from the rectum (back passage), have black sticky bowel motions (stool) or bloody diarrhoea
- you have peptic ulcer (i.e. stomach or duodenal ulcer) or have had one before
- you are using other NSAIDs
- you have chronic constipation or shallow breathing, or severe diarrhoea
- You consume regular and heavy amounts of alcohol.
- You are a CYP2D6 ultra-rapid metaboliser
- If you have severe liver impairment
- If you have heart or kidney problems
- If you are currently taking a Monoamine oxidase inhibitor (MAOIs) or within 14 days of stopping treatment with a MAOI.

Do not take Ibudeine if the packaging is torn or shows signs of tampering.

Do not take Ibudeine if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not give Ibudeine to children under 12 years or to those aged 12-18 years in whom respiratory function may be compromised.

### Check with your doctor if you:

- have or have had any other medical conditions:
- difficulty breathing, wheezing, chronic cough, allergies, asthma or other breathing conditions
- a history of drug dependence, including alcohol dependence
- skin rash (dermatitis)
- skin irritation
- a history of stomach ulcer
- liver disease
- kidney disease
- heart problems/failure, including swelling of ankles or feet
- thyroid problems or low blood pressure

- a head injury or intracranial pressure
- prostatic problems
- stomach problems or recent stomach surgery.
- gave central sleep apnoea (a sleep-related breathing disorder which can cause pauses in breathing during sleep), as a reduced dose of Ibuprofen may be required.

Tell your doctor if you experience severe upper abdominal pain radiating to the back, nausea, vomiting, or fever, as this could be symptoms associated with inflammation of the pancreas and biliary tract system.

Stop use and tell your doctor if you experience side effects including difficulty swallowing, regurgitation, and chest pain, as these may be signs of a problem with your oesophagus.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Ibuprofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 6.

Stop use and tell your doctor if you experience symptoms such as nausea, vomiting, weight loss, fatigue, weakness, dizziness or feeling faint. These may be signs of adrenal insufficiency.

Ibuprofen may cause changes in levels of hormones which may manifest as problems with sexual intercourse including reduced sex drive, as well as changes in the menstrual cycle and reduced fertility.

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**

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

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

Ibuprofen should not be used during pregnancy.

Prolonged use of Ibuprofen at the end of pregnancy may result in withdrawal syndrome in the neonate which may be delayed for several hours to several days after birth. Symptoms in the neonate include stiff muscles, shaking, agitation, convulsions, breathing problems, and slow heartbeat.

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

Ibuprofen should not be taken while breastfeeding.

### **Addiction**

You can become addicted to Ibuprofen even if you take it exactly as prescribed. Ibuprofen may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

### **Dependence**

As with all other opioid containing products, your body may become used to you taking Ibuprofen. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking Ibuprofen suddenly, so it is important to take it exactly as directed by your doctor.

If you are taking Ibuprofen for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 6).

### **Tolerance**

Tolerance to Ibuprofen may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

## **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 Ibuprofen and affect how it works.**

These include:

- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates and sedatives.
- aspirin, salicylates or other NSAID medicines.
- warfarin or other medicines used to prevent blood clots.
- medicines that are used to treat high blood pressure including diuretics (fluid tablets).
- methotrexate.
- zidovudine.
- lithium.
- mifepristone, quinolone antibiotics.
- medicines used to relieve stomach cramps, prevent travel sickness and to treat Parkinson's disease.
- medicines used to treat diarrhoea (e.g. kaolin, pectin, loperamide).
- metoclopramide, a medicine used to treat nausea and vomiting.
- medicines that affect serotonin levels (serotonergic medicines such as triptans, selective serotonin- and norepinephrine- reuptake inhibitors (SNRIs) and tricyclic antidepressants).
- selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression
- 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 neuropathic pain (gabapentinoids such as gabapentin and pregabalin), as they may increase the depressant effects of codeine.

- medicines such as cyclosporin, tacrolimus, prednisone, prednisolone and cortisone which reduce the activity of your immune system.
- probenecid-medicines used to treat gout.
- phenytoin – medicine used to treat epilepsy.
- other opioid pain killers.

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

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

#### 4. How do I use IBUPROFEN?

Follow all directions given to you by your pharmacist or doctor carefully. They may differ from the information contained in this leaflet.

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

##### How much to take and when to take it

- The usual dose of Ibuprofen is 2 tablets then, if necessary 1 or 2 tablets every 4 to 6 hours. Do not take more than six tablets in 24 hours.
- Follow the instructions provided and use Ibuprofen until your doctor tells you to stop.

##### How to take it

- Take Ibuprofen by mouth with fluid. It may also be taken with or immediately after food.

##### How long to take it

- You should not take Ibuprofen for more than three days at a time.

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

**Talk to your doctor about pain control if Ibuprofen is not helping.**

Depending on your body's individual ability to break down codeine, you may be getting reduced benefit or experience signs of overdose even when you take Ibuprofen as recommended by your doctor. If overdose symptoms occur, seek immediate medical advice.

##### If you use too much Ibuprofen

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately and call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used Ibuprofen that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing.

- Drowsiness, dizziness or unconsciousness.
- Slow or weak heartbeat.
- Nausea or upset stomach, vomiting and/or gastric irritation.
- Convulsions, loss of coordination, tremors, weakness, seizures, headaches, vision impairment.
- Excitability.
- Blurred vision, ringing in the ears, or rapid uncontrollable movements of the eyes.

If you think you or someone else may have used too much Ibuprofen, **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.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

#### 5. What should I know while using IBUPROFEN?

##### Things you should do

- If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Ibuprofen.
- Remind any doctor, dentist or pharmacist you visit that you are using Ibuprofen.
- If you are going to have surgery, tell your doctor you are taking Ibuprofen.

Talk to doctor if your symptoms do not improve.

Your doctor will assess your condition and decide if you should continue to take the medicine.

##### Call your doctor straight away if you:

- Become pregnant while taking Ibuprofen.

##### Things you should not do

- Do not take high doses of the medicine for long periods of time unless your doctor tells you to. Products containing codeine should not be taken for prolonged periods. Codeine may be habit forming.
- Do not give Ibuprofen to anyone else, even if they have the same condition as you.
- Do not use Ibuprofen to treat any other complaints unless your doctor tells you to.
- Do not take more than the recommended dose unless your doctor tells you to.
- Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

##### Driving or using machines

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

Ibuprofen may cause dizziness light-headedness or drowsiness in some people. If this occurs, do not drive or operate machinery. If you drink alcohol, dizziness, lightheadedness and/or drowsiness may be worse.

### Drinking alcohol

#### Tell your doctor if you drink alcohol.

Using Ibuprofen with alcohol may result in severe drowsiness, decreased awareness, breathing difficulties, coma and death.

### Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety.
- body aches, weakness or stomach cramps.
- loss of appetite, nausea, vomiting or diarrhoea.
- increased heart rate, breathing rate or pupil size.
- watery eyes, runny nose, chills or yawning.
- increased sweating.

Ibuprofen given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

### Looking after your medicine

- Keep the tablets in the original pack until it is time to take the dose. If you take them out they will not keep well.

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

Store it in a cool dry place where the temperature stays below 30°C 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 medicines where children cannot reach them

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?

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.

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

### Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> <li>• stomach upset including nausea (feeling sick), vomiting</li> <li>• heartburn, indigestion</li> <li>• constipation</li> <li>• diarrhoea, pain in the stomach</li> <li>• loss of appetite</li> </ul> <p>Head and neurology related:</p> <ul style="list-style-type: none"> <li>• sleeplessness, nightmares</li> <li>• change in mood e.g. depression, restlessness, irritability</li> <li>• sore or dry mouth or tongue</li> <li>• dizziness, lightheadedness, drowsiness</li> <li>• headache</li> <li>• hearing disturbance</li> <li>• central sleep apnoea</li> </ul> <p>Respiratory related:</p> <ul style="list-style-type: none"> <li>• shallow breathing</li> <li>• cough suppression</li> <li>• central sleep apnoea</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none"> <li>• severe pain or tenderness in the stomach</li> <li>• vomiting blood or material that looks like coffee grounds.</li> <li>• bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.</li> <li>• pancreatitis and spasm of the sphincter of Oddi (severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever).</li> </ul> <p>Allergy related:</p> <ul style="list-style-type: none"> <li>• shallow breathing or shortness of breath</li> <li>• flushing of the face</li> <li>• swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.</li> <li>• asthma, wheezing, shortness of breath, pain or tightness in the chest</li> <li>• symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal</li> </ul>	<p><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></p>

<p>Heart related:</p> <ul style="list-style-type: none"> <li>fast heart beat, low blood pressure.</li> <li>chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.</li> </ul> <p>Skin related:</p> <ul style="list-style-type: none"> <li>yellowing of the skin and eyes, also called jaundice</li> <li>sudden or severe itching, skin rash, hives, skin peeling</li> <li>severe skin reactions which may present as: <ul style="list-style-type: none"> <li>reddish non-elevated target-like or circular patches on the trunk with blisters, ulcers of the mouth, throat, nose, genitals and eyes; and may be accompanied by fever and flu-like symptoms.</li> <li>widespread rash, high body temperature and enlarged lymph nodes.</li> <li>red scaly rash with bumps under the skin and blisters accompanied by fever.</li> </ul> </li> </ul> <p>Urinary related:</p> <ul style="list-style-type: none"> <li>a change in the colour of urine passed, blood in the urine</li> <li>a change in the amount or frequency of urine passed, burning feeling when passing urine</li> <li>unusual weight gain, swelling of ankles or legs</li> </ul> <p>Infection related:</p> <ul style="list-style-type: none"> <li>signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul> <p>Bleeding related:</p> <ul style="list-style-type: none"> <li>bleeding or bruising more easily than normal, reddish or purplish blotches under the skin</li> <li>signs of anaemia, such as tiredness, being short of breath, and looking pale</li> </ul>	
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<p>Head and neurology related:</p> <ul style="list-style-type: none"> <li>unusual or extreme mood swings</li> <li>dizziness, lightheadedness</li> <li>severe dizziness, spinning sensation</li> <li>severe or persistent headache</li> <li>difficulty hearing, deafness</li> <li>tingling or numbness of the hands or feet</li> </ul> <p>Eyes related:</p> <ul style="list-style-type: none"> <li>eye problems such as blurred vision, sore red eyes, itching</li> </ul>	
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**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.

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 with a doctor's prescription.

### What Ibudeine contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>Ibuprofen and Codeine phosphate hemihydrate</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>Microcrystalline cellulose</li> <li>pregelatinised maize starch</li> <li>croscarmellose sodium</li> <li>colloidal anhydrous silica</li> <li>Opadry complete film coating system OY-58900 white</li> </ul>
<b>Potential allergens</b>	Ibudeine tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Ibudeine tablets do not contain gluten or preservatives.

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

## **What Ibuprofen looks like**

White to off-white capsule-shaped biconvex film-coated tablets. (Aust R 227876).

Each carton contains 20 or 30 film-coated tablets

\* Not all pack sizes may be available.

## **Who distributes Ibuprofen**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

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

This leaflet was prepared in March 2026.