

Ibudeine

(Ibuprofen and Codeine Phosphate Hemihydrate)

Consumer Medicine Information

Please read this leaflet carefully before you start taking Ibudeine tablets.

What is in this leaflet

This leaflet answers some common questions about Ibudeine tablets. 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 Ibudeine tablets against the benefits this medicine is expected to 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 Ibudeine is used for

Ibudeine tablets contain two active ingredients:

Ibuprofen and Codeine phosphate hemihydrate.

Ibuprofen 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.

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

Ibudeine tablets are used for temporary relief of acute moderate pain and inflammation.

About 8% of people are poor metabolisers of codeine and may experience less pain relief with codeine compared with other people.

Ask your doctor if you have any questions about why Ibudeine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Ibudeine is available only with a doctor's prescription.

Before you take Ibudeine

When you must not take it

Do not take Ibudeine if you have an allergy to:

- **Ibuprofen, codeine, or other opioid analgesics such as morphine or pethidine**
- **any of the other ingredients in Ibudeine tablets, listed at the end of this leaflet**
- **aspirin**
- **any other NSAID medicine.**

Symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath.
- swelling of the face, lips, or tongue; this may affect swallowing or breathing.
- hives, itching or skin rash.
- fainting.

If you are allergic to aspirin or any NSAID medicines and take

Ibudeine tablets, symptoms may be severe.

Do not take Ibudeine tablets if you are also taking any other medication that contains one or more NSAID medicine, 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 take Ibudeine tablets during the last 3 months of pregnancy.

It may affect the baby and also delay labour and birth.

Do not take this medicine if you are pregnant, without first consulting your doctor.

Do not take Ibudeine tablets if you are breast-feeding or planning to breast-feed.

This medicine passes into breast milk and may affect the baby. If you require Ibudeine therapy, breast-feeding should be stopped and alternative arrangements should be made for feeding the baby during the treatment period.

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

Do not take this medicine if you are aged between 12 to 18 years of age and have had your tonsils or adenoids removed to treat sleep apnoea.

Do not take Ibudeine:

- if you have recently vomited blood or material that looks like coffee grounds

- if you have recently bled from the rectum (back passage), had black sticky bowel motions (stools) or bloody diarrhoea
- if you have diarrhoea caused by poisoning or antibiotics
- if you have a stomach 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 conditions involving an increased tendency to bleeding (such as taking medicines used to prevent blood clots), or active bleeding
- if you have or have had liver failure
- if you have kidney disease
- if you have or have had heart failure
- if you have asthma that is sensitive to aspirin or NSAIDs
- if you have chronic constipation or shallow breathing
- if you have acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- if you consume heavy amounts of alcohol regularly
- if you are a CYP2D6 ultra-rapid metaboliser
- if the packaging is torn or shows signs of tampering
- if the expiry date (EXP) printed on the pack has passed.

If you are not sure whether you should start taking Ibudeine tablets, talk to your pharmacist or doctor.

Before you start to take it

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

Tell your doctor or pharmacist:

- **if you are pregnant or are planning to become pregnant.** Ibudeine may affect your developing baby. Your doctor or pharmacist will discuss the

benefits and possible risks of taking it during pregnancy.

- if you have or have had any of the following medical conditions:
 - stomach or duodenal ulcer
 - liver disease
 - kidney disease or difficulty urinating
 - heart problems
 - swelling of ankles or feet
 - asthma
 - a breathing disorder
 - signs of gastrointestinal bleeding, such as vomiting blood or bleeding from the back passage (rectum)
 - Addison's disease (low activity of the adrenal gland)
 - an underactive thyroid gland
 - a history of drug dependence, including alcohol dependence
 - you drink large quantities of alcohol
 - low blood pressure
 - fits or seizures
 - a head injury, intracranial pressure, or brain tumour
 - prostate problems
 - stomach problems, bowel problems or severe inflammatory bowel disease
 - recent stomach, intestine, or urinary tract surgery

If you have not told your doctor or pharmacist about any of the above, tell her/him before you start taking Ibudeine.

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 ibuprofen and codeine may interfere with each other. These include:

- any medicine causing sleepiness or drowsiness
- central nervous system (CNS) depressants, such as tranquillisers, sedatives, pain killers, barbiturates, medicines

to help you sleep or relieve anxiety

- aspirin, salicylates or other non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin or other medicines used to prevent blood clots
- medicines which thin the blood
- medicines used to lower blood pressure, e.g. diuretics (fluid tablets)
- medicines used to treat heart failure
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- zidovudine, a medicine used to treat HIV infection
- cholestyramine (a medicine used to treat bile problems and/or high cholesterol)
- quinidine (a medicine used to treat abnormal or irregular heartbeat)
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used to treat depression or anxiety
- monoamine oxidase inhibitors (medicines for treating depression or mood swings, such as tranlycypromine or moclobemide), even if taken within the last 14 days
- medicines used to treat diabetes
- medicines used to relieve stomach cramps
- medicines containing alcohol (ethanol), e.g. some cough syrups
- medicines used to treat diarrhoea (e.g. kaolin, pectin, loperamide)
- metoclopramide

- other pain relieving medicines, including other opioids.

The above medicines may be affected by medicines containing Ibuprofen and Codeine 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 or pharmacist will advise you.

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

How to take Ibudeine

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

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

How much to take

The usual dose for adults and children over 12 years of age is 2 tablets followed by, if necessary, 1 or 2 tablets every 4 hours. **Do not take more than 6 tablets in 24 hours.**

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

Talk to your doctor about pain control if the medicine is not helping.

If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

How to take it

Swallow the tablets with fluid. It may be taken before, or after, food.

How long to take it

You should not take Ibudeine tablets for more than a few days.

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

If you forget to take it

If it is almost time for 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 pharmacist or doctor.

If you take too much (overdose)

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

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.

While you are taking Ibudeine

Things you must do

- If you become pregnant while taking Ibudeine tell your doctor immediately.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ibudeine.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Ibudeine.
- If you are going to have surgery, tell your doctor you are taking Ibudeine.

Things you must not do

- Do not give Ibudeine to anyone else, even if they have the same condition as you.
- Do not take Ibudeine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not take Ibudeine with any other product containing ibuprofen/other NSAID and/or codeine/other opioid unless your doctor tells you.

Things to be careful of

- Be careful driving or operating machinery until you know how Ibudeine affects you.
- Ibudeine 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.

Be careful drinking alcohol while taking Ibudeine. Drinking alcohol increases the likelihood of becoming drowsy and it could make some of the unwanted side effects of Ibudeine worse.

Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking this medicine.

Products containing codeine should not be taken for prolonged periods; codeine may be habit forming.

Side Effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while taking Ibudeine, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

This medicine 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 these side effects.

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

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

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

- stomach upset including nausea (feeling sick), vomiting
- heartburn, indigestion
- diarrhoea, stomach pain
- loss of appetite
- dizziness, light-headedness, drowsiness
- nervousness
- constipation
- shallow breathing
- cough suppression
- headache
- skin rashes
- hearing disturbance.

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

If any of the following happen, stop taking Ibudeine and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 or other parts of the body.
- asthma, wheezing, shortness of breath, pain or tightness in the chest, or difficulty breathing
- sudden or severe itching, skin rash, hives, skin peeling
- fast or irregular heartbeat
- difficulty in urinating (passing water)
- blurred or double vision
- easy bruising

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Some people may get other side effects while taking Ibudeine.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

After taking Ibudeine

Storage

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

If you take them out they will not keep as well.

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

Do not store Ibudeine or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a windowsill.

Heat and dampness can destroy some medicines.

Keep the tablets 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.

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What it looks like

Ibudeine tablets are white to off-white capsule-shaped, biconvex, film-coated tablets.

Ingredients

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

Each tablet also contains:

- lactose monohydrate
- Maize starch
- glyceryl behenate
- Colloidal anhydrous silica
- magnesium stearate
- hypromellose, titanium dioxide (171) and macrogol in the coating.

Ibudeine tablets do not contain gluten or preservatives.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

This leaflet was updated in November 2018.

The information provided applies only to: Ibudeine, AUST R 158210.