

MEDICHOICE IBUPROFEN 400MG 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. [Include if applicable]

1. Why am I using MEDICHOICE IBUPROFEN 400 MG TABLETS?

MEDICHOICE IBUPROFEN 400MG TABLETS contains the active ingredient Ibuprofen. MEDICHOICE IBUPROFEN 400MG TABLETS is used to relieve pain and reduces inflammation (swelling, redness or soreness).

For more information, see Section [MEDICHOICE IBUPROFEN 400MG TABLETS?](#) in the full CMI.

2. What should I know before I use MEDICHOICE IBUPROFEN 400 MG TABLETS?

Do not use if you have ever had an allergic reaction to MEDICHOICE IBUPROFEN 400MG TABLETS or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use MEDICHOICE IBUPROFEN 400MG TABLETS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MEDICHOICE IBUPROFEN 400MG TABLETS 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 MEDICHOICE IBUPROFEN 400 MG TABLETS?

- The usual daily dose of MEDICHOICE IBUPROFEN 400MG TABLETS for adults and children over 12 years of age is one tablet taken three times a day. Do not take more than three tablets in 24 hours.

More instructions can be found in Section [4. How do I use MEDICHOICE IBUPROFEN 400MG TABLETS?](#) in the full CMI.

5. What should I know while using MEDICHOICE IBUPROFEN 400 MG TABLETS?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist or pharmacist you visit that you are using MEDICHOICE IBUPROFEN 400MG TABLETS. If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> Do not take any other medicines to relieve pain and reduce inflammation while you are taking MEDICHOICE IBUPROFEN 400MG TABLETS without first telling your doctor or to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none"> MEDICHOICE IBUPROFEN 400MG TABLETS may cause dizziness or light-headedness, drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous
Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol while taking MEDICHOICE IBUPROFEN 400MG TABLETS.
Looking after your medicine	<ul style="list-style-type: none"> Keep the tablets in a cool dry place where the temperature stays below 30°C. Do not store IBUPROFEN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

For more information, see Section [5. What should I know while using MEDICHOICE IBUPROFEN 400MG TABLETS?](#) in the full CMI.

6. Are there any side effects?

[Nausea, appetite, heartburn, headache, etc. These are common side effects of your medicine. They are usually mild.]

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.

MEDICHOICE IBUPROFEN 400 MG TABLETS

Active ingredient(s): *Ibuprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MEDICHOICE IBUPROFEN 400MG TABLETS. **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 MEDICHOICE IBUPROFEN 400MG TABLETS.**

Where to find information in this leaflet:

[1. Why am I using MEDICHOICE IBUPROFEN 400MG TABLETS?](#)

[2. What should I know before I use MEDICHOICE IBUPROFEN 400 MG TABLETS?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use MEDICHOICE IBUPROFEN 400 MG TABLETS?](#)

[5. What should I know while using MEDICHOICE IBUPROFEN 400 MG TABLETS?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. WHY AM I USING MEDICHOICE IBUPROFEN 400 MG TABLETS

MEDICHOICE IBUPROFEN 400MG TABLETS contains the active ingredient *Ibuprofen*. *MediChoice Ibuprofen 400 mg* Tablets belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

MEDICHOICE IBUPROFEN 400MG TABLETS is used for the temporary relief of pain and discomfort associated with:

- migraine
- tension headaches
- muscular aches
- dental pain
- Pains associated with colds and flu.
- Period pain
- Arthritic pain.

Reduces fever.

2. What should I know before I use MEDICHOICE IBUPROFEN 400 MG TABLETS?

Warnings

Do not use MEDICHOICE IBUPROFEN 400MG TABLETS if you are allergic to *Ibuprofen*, aspirin or any other NSAID medicine or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of 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
- hives, itching or skin rash
- Stomach ache, fever, chills, nausea and vomiting.
- fainting

If you get an allergic reaction, stop taking and see your doctor immediately.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist. If you are allergic to aspirin or any other NSAID medicines and take IBUPROFEN, these symptoms may be severe.

Do not take IBUPROFEN if:

1. you are in the last 3 months of pregnancy.
2. you have (or have previously) vomited blood or material that looks like coffee grounds.
3. you are (or have previously) bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
4. you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.
5. you have heart failure
6. you have severe liver disease
7. you have kidney disease
8. you have asthma that is sensitive to aspirin or NSAIDs.
9. you are undergoing treatment of pain following heart bypass surgery.

Check with your doctor or pharmacist if:

- you have any allergies to any other substances, such as medicines, foods, preservatives or dyes
- you take any medicines for any other condition
- you have or have had any other medical conditions, especially the following:
 - heart disease or high blood pressure
 - heartburn, indigestion, stomach ulcer or any other stomach problems
 - vomiting blood or bleeding from the back passage
 - severe skin reactions such as Stevens-Johnson syndrome
 - Asthma and have not previously taken an NSAID
 - Vision problems
 - Liver or kidney disease
 - tendency to bleed or other blood problems
 - Bowel or intestinal problems such as ulcerative colitis or Crohn's Disease
 - Heart failure
 - swelling of the ankles or feet
 - Diarrhoea

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. IBUPROFEN may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. Small amounts of ibuprofen pass into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

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 MEDICHOICE IBUPROFEN 400 MG TABLETS and affect how it works.

These include

- aspirin, salicylates or other NSAID medicines.
- warfarin, medicines used to stop blood clots.
- lithium, a medicine used to treat some types of depression.
- SSRIs such as sertraline, medicines used to treat depression.
- Various medicines used to treat high blood pressure or other heart conditions.
- medicines used to treat heart failure such as digoxin
- diuretics, also called fluid tablets.
- methotrexate, a medicine used to treat arthritis and some types of cancer.
- corticosteroids, such as prednisone, cortisone.
- ciclosporin or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection.
- aminoglycosides, medicines used to treat certain infections.
- Gingko biloba, an herbal medicine used to thin the blood.
- quinolone antibiotics, medicines used to treat certain infections.
- zidovudine, a medicine used to treat HIV.
- colestyramine, a medicine used to treat high cholesterol.
- sulfonylureas, medicines to treat diabetes.
- voriconazole or fluconazole, medicines to treat certain fungal infections.
- mifepristone (RU-486), a medicine used to end a pregnancy.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MEDICHOICE IBUPROFEN 400MG TABLETS.

4. How do I use MEDICHOICE IBUPROFEN 400 MG TABLETS?

Adults and children over 12 years: one tablet with fluid every 4-6 hours, as necessary.

Do not take more than three tablets in 24 hours.

- Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.

If you use too much MEDICHOICE IBUPROFEN 400 MG TABLETS

If you think that you have used too much MEDICHOICE IBUPROFEN 400MG TABLETS, you may need urgent medical attention.

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.

5. What should I know while using MEDICHOICE IBUPROFEN 400 MG TABLETS?

Things you should not do

- **Do not take any other medicines to relieve pain and reduce inflammation while you are taking IBUPROFEN without first telling your doctor or pharmacist.**

This includes:

- aspirin (also called acetylsalicylic acid)
- other medicines containing ibuprofen, the active ingredient in IBUPROFEN
- any other NSAID medicine

Do not take MEDICHOICE IBUPROFEN 400MG TABLETS to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful driving, operating machinery or using tools until you know how MediChoice Ibuprofen 400 mg Tablets affect you. This medicine may cause dizziness in some people. If this happens, do not drive, operate machinery or use tools.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol may increase NSAID-related undesirable effects.

Elderly patients

If you are over 65 years of age, talk to your pharmacist or doctor about taking this medicine. Taking this medicine may increase the risk of you getting unwanted effects, such as stomach or heart problems.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well
- Store it in a cool dry place where the temperature stays below 30°C away from moisture, heat or sunlight.

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.

When to discard your medicine

Discard the medicine if the expiry date has passed

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 has passed.

6. Are there any side effects?

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking MediChoice Ibuprofen 400 mg Tablets.

This medicine helps most people with pain or fever, 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 pharmacist or doctor to answer any questions you may have. It is rare to get side effects from ibuprofen if taken for a short period of time and in the doses in over-the-counter medicines.

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

- nausea, heartburn, or stomach pain,
- loss of appetite,
- diarrhoea,
- dizziness,
- drowsiness,
- headache,
- nervousness.

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

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

- get sunburnt more quickly than usual.

The above 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.

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

- fluid retention,
- 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.

The above 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 pharmacist or doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also 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.

7. Product details

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

What MEDICHOICE IBUPROFEN 400 MG TABLETS contains

Active ingredient (main ingredient)	Ibuprofen
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Maize starch• Pregelatinised starch• Purified water• Colloidal anhydrous silica• Magnesium stearate• Hypromellose (HPMC 6CP)• Purified talc• Macrogol 6000• Titanium dioxide• Erythrosine aluminium lake

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

What MEDICHOICE IBUPROFEN 400MG TABLETS looks like

MediChoice Ibuprofen 400mg Tablets :pink coloured, round shaped, biconvex film-coated tablets, plain on both

sides.

The tablets are available in a PVC-Aluminium blister in packs of 10, 20, or 30 tablets.

Who distributes MEDICHOICE IBUPROFEN 400 MG TABLETS?

Nova Pharmaceuticals

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