

## APO-Ibuprofen 400

Ibuprofen 400mg

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about APO-Ibuprofen 400. 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 pharmacist or doctor has weighed the risks of you taking APO-Ibuprofen 400 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 APO-Ibuprofen 400 is used for

Ibuprofen is used for the temporary relief of 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
- arthritis
- rheumatic pain, and
- the aches and pains associated with colds and flu

It also reduces fever.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

**Ask your pharmacist or doctor if you have any questions about this medicine.**

Your pharmacist or doctor may have given it to you for another reason.

APO-Ibuprofen 400 is only available from your pharmacist.

APO-Ibuprofen 400 is not addictive.

#### Before you take APO-Ibuprofen 400

##### *When you must not take it*

**Do not take APO-Ibuprofen 400 if you have an allergy to:**

- any medicine containing ibuprofen, aspirin or other NSAIDs
- 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 NSAID medicines. If you are not sure if you are taking any of these medicines, ask your pharmacist.

Some of the symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty breathing
- hives, itching or skin rash

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

**If you are allergic to aspirin or NSAID medicines and take APO-Ibuprofen 400, these symptoms may be severe.**

**Do not take APO-Ibuprofen 400 if you have:**

- asthma that is sensitive to aspirin or NSAIDs
- a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- recently (or have previously) vomited blood or material that looks like coffee grounds
- recently (or previously) bled from the back passage (rectum), had black sticky bowel motions (stools) or bloody diarrhoea
- a condition resulting in an increased tendency to bleed
- or have a history of, Ulcerative Colitis or Crohn's Disease
- severe kidney disease
- severe heart failure
- severe liver disease
- are being treated for pain following heart bypass surgery

**Do not take APO-Ibuprofen 400 if you are pregnant, or intend to become pregnant or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all in the last three months of pregnancy.**

It may affect your developing baby if you take it during pregnancy.

**Do not take APO-Ibuprofen 400 after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If this medicine has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking APO-Ibuprofen 400, talk to your pharmacist or doctor.**

*Before you start to take it*

**Tell your pharmacist or doctor if you have allergies to:**

- any other medicines including aspirin or other NSAID medicines,
- any other substances, such as foods, preservatives or dyes.

**Tell your pharmacist or doctor if you are pregnant or intend to become pregnant.**

Like most NSAID medicines, APO-Ibuprofen 400 is not recommended to be used during pregnancy. It may also impair female fertility.

**Tell your pharmacist or doctor if you are breast-feeding or plan to breast-feed.**

Like most NSAID medicines, APO-Ibuprofen 400 is not recommended while you are breast-feeding.

**Tell your pharmacist or doctor if you have or have had any of the following medical conditions especially the following:**

- asthma

- 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
- vision problems
- liver or kidney disease
- tendency to bleed or other blood problems
- bowel or intestinal problems such as ulcerative colitis
- heart failure
- swelling of ankles or feet
- diarrhoea

**Talk to your pharmacist or doctor about taking APO-Ibuprofen 400 if you are over 65 years of age.**

**Tell your doctor or pharmacist if you currently have an infection.**

If you take APO-Ibuprofen 400 while you have an infection, it may hide some of the signs and symptoms of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

**Tell your doctor or pharmacist if you plan to have surgery.**

**If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking APO-Ibuprofen 400.**

##### *Taking other medicines*

**Tell your pharmacist or doctor 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 may interfere with each other. These include:**

- warfarin or clopidogrel, medicines used to stop blood clots
- lithium, a medicine used to treat mood swings and some types of depression
- SSRIs such as sertraline, medicines used to treat depression
- medicines used to treat high blood pressure or other heart conditions
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure such as digoxin
- medicines such as prednisone, prednisolone and cortisone, which reduce the activity of your immune system
- cyclosporine 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
- quinolone antibiotics, medicines used to treat certain infections
- mifepristone, a medicine used to bring about an abortion

- zidovudine, a medicine used to treat HIV infection
- aspirin, salicylates and other non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines used to treat diabetes
- probenecid, a medicine used to treat gout
- phenytoin, a medicine used to treat epilepsy.

These medicines may be affected by APO-Ibuprofen 400, 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 doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking APO-Ibuprofen 400.

---

### How to take APO-Ibuprofen 400

---

**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 container, ask your pharmacist or doctor for help.**

#### *How much to take*

Adults and Children from 12 years: One tablet every 4 to 6 hours as necessary.

**Do not take more than 3 tablets in 24 hours.**

**Do not give to children under 12.**

**Do not take more than the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.**

#### *How to take it*

Take APO-Ibuprofen 400 by mouth with water.

#### *How long to take it*

Medreich Ibuprofen 400 Double Strength should not be used for more than 3 days at a time, except on medical advice.

**Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage.**

#### *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 APO-Ibuprofen 400. Do this even if there are no signs of discomfort or poisoning.**

---

### While you are using APO-Ibuprofen 400

---

#### *Things you must do*

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

**If you are about to start taking any new medicine tell your doctor or pharmacist that you are taking this medicine.**

**Tell all of your doctors, dentists, and pharmacists that are treating you that you are taking APO-Ibuprofen 400.**

**If you are going to have surgery, make sure the surgeon and anaesthetist know you are taking APO-Ibuprofen 400.**

NSAID medicines can slow down blood clotting.

**Tell your pharmacist or doctor if your symptoms do not improve. Your pharmacist or doctor will assess your conditions and decide if you should continue to take the medicine.**

#### *Things you must not do*

**Do not take APO-Ibuprofen 400 with any other medicines containing ibuprofen, aspirin or other anti-inflammatory medicines unless your doctor tells you to.**

**Do not take APO-Ibuprofen 400 to treat any other complaints unless your pharmacist or doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

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

#### *Things to be careful of*

**If you are over 65 years of age, talk to your pharmacist or doctor about taking APO-Ibuprofen 400.**

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

**Be careful driving or operating machinery until you know how APO-Ibuprofen 400 affects you.**

This medicine may cause dizziness in some people. If this happens, do not drive or operate machinery.

---

### Side effects

---

**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking APO-Ibuprofen 400.**

This medicine may have unwanted side effects in a few people. As with most medicines, if you are over 65 years of age, you may have an increased chance of getting side effects.

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 non-prescription (over-the-counter) medicines.

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

- nausea or vomiting
- heartburn, or pain in the upper part of your stomach
- loss of appetite
- cramps, wind, constipation or diarrhoea
- dizziness
- sleepiness
- buzzing or ringing in the ears or other trouble hearing
- headache

- sleeplessness,
- changes in mood, for example depression, confusion, nervousness

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

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

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, headaches, being short of breath and looking pale
- yellowing of the skin and/or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- tingling of the hands and feet
- symptoms of sunburn (such as redness, itching swelling, blistering) which may occur more quickly than usual
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations

The above side effects may be serious and may require urgent 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, stop taking APO-Ibuprofen 400 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
- shortness of breath
- asthma, wheezing or difficulty breathing
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- Sudden or severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck

This medicine may be associated with a small increased risk of heart attack (myocardial infarction)

Blood disorders and kidney problems may occur with this medicine.

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.

---

## After using APO-Ibuprofen 400

---

### *Storage*

**Keep your medicine in the original pack until it is time to take.**

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

**Do not store APO-Ibuprofen 400 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

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*

**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*

APO-Ibuprofen 400 tablets are white to off-white, pillow-shaped, film coated tablets plain on both sides.

### *Packaging*

APO-Ibuprofen 400 is available in cartons with PVC/Aluminium blister packs containing 10, 20, or 30, tablets\*

\* Not all pack sizes may be marketed.

### *Ingredients*

APO-Ibuprofen 400 tablets contain 400 mg of ibuprofen as the active ingredient.

Each tablet also contains:

- Lactose monohydrate,
- Cellulose microcrystalline,
- Povidone,
- Croscarmellose sodium,
- Sodium lauryl sulfate,
- Colloidal silica anhydrous,
- Stearic acid,
- Macrogol 6000,
- Hypromellose,
- Titanium dioxide
- Talc purified

This medicine does not contain gluten, wheat, sucrose or preservatives.

### *Australian Registration Numbers*

APO- Ibuprofen 400 tablets (blister):  
AUST R 289218.

### *Sponsor*

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113  
AUSTRALIA

This leaflet was prepared in May 2017