

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400

Ibuprofen 400 mg

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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 doctor has weighed the risks of you taking CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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 CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 IS USED FOR

Ibuprofen relieves pain and reduces inflammation (swelling, redness or soreness) that may occur:

- in different types of arthritis including rheumatoid arthritis, osteoarthritis and juvenile rheumatoid arthritis
- in muscle and bone injuries such as sprains, strains, lower backpain (lumbago), rheumatism, and tendonitis, such as tennis elbow
- from swelling and pain after setting broken or dislocated bones
- menstrual cramps (period pain)
- following surgery
- due to dental pain

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 also relieves fever (high temperature).

Although CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 can relieve the symptoms of pain and inflammation, it will not cure your condition.

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

Ask your doctor if you have any questions about why CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 has been prescribed for you.

Your doctor may have prescribed CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 for another reason.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400

When you must not take it

Do not take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 if you have an allergy to:

- any medicines containing ibuprofen, aspirin or other NSAIDs;
- any of the ingredients listed at the end of this leaflet;

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; and
- rash, itching or hives on the skin
- stomach ache, fever, chills, nausea and vomiting
- fainting.

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 CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400, these symptoms may be severe.

Do not take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 if:

1. **you are pregnant or intend to become pregnant.**
CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 may affect your baby if you take it during pregnancy.
2. **you are breastfeeding or intend to breastfeed.**
CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 passes into breastmilk and may affect you baby.
3. **you have (or have recently) vomited blood or material that looks like coffee grounds**
4. **you are (or have previously) bleeding from the back passage (rectum), have black sticky bowel motions (stools) or bloody diarrhoea**
5. **you have a condition resulting in an increased tendency to bleed**
6. **you have a peptic ulcer (i.e. a stomach or duodenal ulcer) a recent history of one, or have had peptic ulcers before**
7. **you have, or have a history of, Ulcerative Colitis or Crohn's Disease**
8. **you have severe heart failure**
9. **you have severe liver disease**
10. **you have severe kidney disease**

Do not take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 after the expiry date printed on the pack or if the package is torn or shows sign 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 CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if:

1. **you have allergies to:**
any other substances such as medicines, foods, preservatives or dyes
2. **you are pregnant or intend to become pregnant**
Like most NSAID medicines, CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 is not

recommended to be used during pregnancy.

It may also impair female fertility.

3. **you are breastfeeding or plan to breastfeed**

Like most NSAID medicines, CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 is not recommended while you are breastfeeding.

4. **you have had any 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
- 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.

5. **you currently have an infection**

If you take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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.

6. **you plan to have surgery**

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.

Before you start to take it

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:

- aspirin, salicylate and other non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin, a medicine used to prevent 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
- 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, prednisolone and cortisone, which

reduce the activity of your immune system

- 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, a herbal medicine to thin blood
- quinolone antibiotics, medicines used to treat certain infections
- zidovudine, a medicine used to treat HIV infection
- cholestyramine, a medicine used to treat high cholesterol
- sulfonylureas, medicines used to treat diabetes
- voriconazole or fluconazole, medicines to treat certain fungal infections
- mifepristone (RU-486), a medicine used to end pregnancy.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while using CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.

HOW TO TAKE CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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 box, 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.

How to take it

Take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 by mouth with water. Do not chew the tablets.

How long to take it

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 should not be used for more than 3 days at a time, except on medical advice.

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 CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.

Tell any other doctors, dentists and pharmacists that are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

NSAID medicines can slow down blood clotting.

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

If you get an infection while taking this medicine, tell your doctor.
CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 may hide some of the signs of an infection and may make you think mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if you get any visual disturbances such as blurred vision.

You may need to have an eye examination to make sure CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 is not causing any side effects.

Things you must not do

Do not take any other medicines to relieve pain and reduce inflammation while you are taking CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 without first telling your doctor.

This includes:

- aspirin (also called acetylsalicylic acid)
- other medicines containing ibuprofen, the active ingredient in CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400
- any other NSAID medicine

Do not take CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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 the 65 years of age, talk to your pharmacist or doctor about taking CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.

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

Be careful driving or operating machinery until you know how CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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 CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.

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 lists of side effects. You may not experience any of them.

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

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;
- drowsiness;
- headache;
- buzzing or ringing in the ears or other trouble hearing;
- sleeplessness;
- changes in mood, for example feeling anxious, depression, confusion, or 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:

- 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 normal
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations.

The above side effect may be serious and 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:

- 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
- asthma, wheezing, shortness of breath
- 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
- hearing difficulties, ringing in the ears.

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 may be associated with a small increased risk of heart attack (myocardial infarction).

Blood disorders and kidney problems may occur with **CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400.**

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 TAKING CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400

Storage

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

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 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

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 tablets are pink colour, round, biconvex film-coated tablets (may have minor colour specs on tablet surface) debossed with "I 400" on one side and plain on the other side.

Ingredients

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 tablets contain 400 mg ibuprofen as the active ingredient.

Each tablet also contains:

- maize starch;
- croscarmellose sodium;
- povidone;
- colloidal anhydrous silica;
- sodium starch glycollate;

- magnesium stearate;
- hypromellose;
- purified talc;
- titanium dioxide;
- macrogol 6000; and
- FD&C Red 40 aluminium lake.

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

Packaging

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400 is available in blister packs* of 2, 4, 10, 12, 20, 24, 30, 36, 40, 48 and 50 tablets.

*Not all pack sizes are marketed.

Supplier

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

Australian Registration Numbers

CHEMISTS' OWN IBUPROFEN DOUBLE STRENGTH 400:

400 mg - AUST R 289396

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