

Information for the user



Ibuprofen 400mg Tablets

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

This medicine contains Ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which act to relieve pain and reduce swelling. It can be used to relieve headaches, rheumatic and muscular pain, pain from non-serious arthritic conditions, backache, migraine, period pain, dental pain and neuralgia. It can also be used to reduce fever and relieve the symptoms of colds and flu.

Before you take this medicine

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

X Do not take if you:

- **have a stomach ulcer, perforation or bleeding**, or have had one twice or more in the past
- **have had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- **are allergic** to ibuprofen or any other ingredients of this medicine, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **are taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines
- **have severe heart, kidney or liver failure**
- **are pregnant**, and in the last 3 months of pregnancy

Other important information

If you are taking Ibuprofen 400mg Tablets 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 'Possible side effects').

Risk of heart attack or stroke:

Anti-inflammatory/painkiller medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

Take special care with Ibuprofen 400mg Tablets.

Skin reactions: Serious skin reactions have been reported in association with ibuprofen treatment. You should stop taking this medicine and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See "Possible Side Effects".

! Talk to your pharmacist or doctor:

- If you have asthma, a history of asthma or other allergic disease, bowel problems, ulcerative colitis, Crohn's disease
- If you have other kidney, heart or liver problems (see "Do not take")
- If you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
- If you have chickenpox
- If you are elderly – you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA") – see '**Risk of heart attack or stroke**' under "Other important information"
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- **Children and adolescents:** If you are between 12 and 18 years old and you are dehydrated – you may get kidney problems
- If you have an infection – please see section "infections" below

Other information

Infections

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 400mg Tablets may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

If you take other medicines

Before you take these tablets, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time. Ibuprofen may affect or be affected by some other medicines. For example:

- Other painkillers (including NSAIDs)
 - Aspirin 75 mg (to prevent heart attacks or strokes) – the protection may be reduced when you take ibuprofen
 - Medicines to thin your blood (e.g. warfarin, ticlopidine)
 - Mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days
 - Water tablets (diuretics)
 - Medicines to treat high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines for heart problems
 - Corticosteroids, lithium, methotrexate, zidovudine
 - Quinolone antibiotics (for infections)
 - Medicines for depression (including SSRIs)
 - Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)
- Some other medicines may also affect or be affected by the treatment of ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with any other medicines, including herbal and homeopathic remedies.

Pregnancy: Do not take this medicine if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and

cause labour to be later or longer than expected.

You should not take this medicine during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, this medicine can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding: If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing age: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop the medicine.

Important information about some of the ingredients of this medicine

This medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

✓ How to take this medicine

Check the foil is not broken before use. If it is, do not take that tablet.

Adults and children of 12 years and over: Take one tablet every 4 hours, if you need to. **Don't take more than 3 tablets in 24 hours.** Take the lowest amount for the shortest possible time to relieve your symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section Infections).

Swallow each tablet with water. Do not give to children under 12 years. Do not take more than the amount recommended above.

In adults: If your symptoms worsen or do not go away within 10 days, talk to your doctor.

In children and adolescents (aged 12-18 years old): If this medicinal product is required for more than 3 days, or if symptoms worsen, talk to your doctor.

! If you take more tablets than you should: If you have taken more tablets than you should, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion on the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

Possible side effects

Most people will not have problems, but some may get some.

If you are elderly you may be more likely to have some of these side effects.

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or

unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)

- Stomach problems including pain, indigestion or heartburn
- Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reactions)
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- Frequency "Not known": A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop taking this medicine if you develop these symptoms and seek medical attention immediately. See also "Before you take this medicine"
- Worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- Meningitis (e.g. stiff neck, fever, disorientation)
- High blood pressure, heart failure (you may be tired, have difficulty breathing or swollen legs)
- A small increased risk of heart attack or stroke if you take large amounts for a long time
- Yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Swellings or ulcers of the stomach
- Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

If you get any of the following side effects see your pharmacist or doctor:

- Uncommon, feeling sick or rarely, being sick
- Uncommon, headache
- Rarely, diarrhoea, constipation and wind, and very rarely, worsening of colitis or Crohn's disease
- Frequency not known, swellings or ulcers of the mouth lining, fluid retention, which may cause swelling of the limbs, skin becomes sensitive to light.

Ibuprofen 400mg Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 'Other important information'). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

How to store this medicine

Store below 25°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton.

What is in this medicine

Each tablets contains Ibuprofen 400 mg, which is the active ingredient.

As well as the active ingredient, the tablets also contain microcrystalline cellulose, lactose monohydrate, hypromellose, croscarmellose sodium, sodium laurilsulfate, magnesium stearate, french chalk, colloidal silicon dioxide, titanium dioxide (E171).

The pack contains 24, 48 or 96 white capsule shaped tablets. Not all pack sizes may be marketed.

Who makes this medicine

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA.

Manufacturer responsible for batch release: The Boots Company PLC Nottingham NG90 1BS.

Leaflet prepared December 2022.

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Artwork reference number: 1048002