

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 **in adults and adolescents weighing from 40kg (12 years of age and above)** 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 or ever had a stomach ulcer, perforation or bleeding**
- have had a gastrointestinal bleeding or perforation, related to previous use of NSAIDs (Non-Steroidal Anti-Inflammatory Drugs)
- **are allergic** to ibuprofen or any other ingredients of this medicine, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had chest pain, 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**, if you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine
- **have severe heart, kidney or liver failure, high blood pressure, or blood coagulation disorder**
- **are pregnant**, and in the last 3 months of pregnancy
- **have breathing difficulties**
- **are under 12 years old**

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').

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop taking this medicine immediately and immediately contact your doctor or medical emergency department if you notice any of these signs.

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.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section '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. This medicine 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.

Other information

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 e.g. cardiac glycoside (such as digoxin)
- 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

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below). If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects. **STOP TAKING this medicine and seek immediate medical help if you develop:**

- signs of intestinal bleeding such as: bright red faeces (stools/motions), black tarry stools, vomiting, blood or dark particles that look like coffee grounds.
- signs of serious allergic reaction such as difficulties in breathing and unexplained wheezing, dizziness or faster heartbeat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Stevens-Johnson syndrome), swelling of your face, tongue or throat, drop in blood pressure leading to shock
- signs of kidney problems such as: passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)
- signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness. Patients with autoimmune disorders (lupus, mixed connective tissue disease) may be more likely to be affected
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis]
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). See also section 'Other important information'

STOP taking this medicine and tell your doctor if you experience the following uncommon side effects, which may affect up to 1 in 100 people:

- indigestion, heartburn or feeling sick
- pains in your stomach (abdomen) or other abnormal stomach problems

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed:

Uncommon: may affect up to 1 in 100 people

- allergic reactions, such as skin rashes (urticarial), itching, peeling
- headaches

Rare: may affect up to 1 in 1,000 people

- flatulence (wind), diarrhoea, constipation and vomiting

Very rare: may affect up to 1 in 10,000 people

- blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure

- stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)

- liver problems

Not known: frequency cannot be estimated from the data

- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn's disease
- skin becomes sensitive to light

Any anti-inflammatory / pain-killer medicines such as this medicine may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine 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') - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker

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.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please stop taking the product immediately and tell your doctor or pharmacist.

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.

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

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