

Package leaflet: Information for the user

## IBUPROFEN 400MG TABLETS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

**What is in this leaflet:**

1. What Ibuprofen Tablets are and what are they used for
2. What you need to know before you take Ibuprofen Tablets
3. How to take Ibuprofen Tablets
4. Possible side effects
5. How to store Ibuprofen Tablets
6. Contents of the pack and other information

### 1. What Ibuprofen Tablets are and what they are used for

The active substance used in these tablets is Ibuprofen.

Ibuprofen belongs to a group of medicines called the non-steroidal anti-inflammatory drugs (NSAIDs), which helps relieve pain, reduces inflammation and lowers temperature when you have a fever.

These tablets are used to treat rheumatic or muscular pain, pain of non-serious arthritis, backache, neuralgia, migraine, headache, dental pain, and period pains. They are also used for the relief of feverishness, colds and influenza.

### 2. What you need to know before you take Ibuprofen Tablets

**Do not take these tablets if you:**

- have ever been told you are allergic to ibuprofen, aspirin, other non-steroidal anti-inflammatory drugs, or to any of the other ingredients (listed in section 6).
- have had perforation or a bleeding stomach after taking non-steroidal anti-inflammatory medicines (you may have been sick and it contained blood or dark particles that looked like coffee grounds, passed blood in your stools or passed black tarry stools)
- have a stomach ulcer, perforation or bleeding, or have had one twice or more in the past
- suffer from severe heart, liver or kidney problems
- are in the last 3 months of pregnancy
- have had a skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.

- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal anti-inflammatory drugs)
- have breathing difficulties
- are under 12 years of age
- are taking other NSAID pain killers or more than 75mg aspirin a day.

**Warnings and Precautions**

Talk to your doctor or pharmacist if you:

- suffer from asthma, or have a past history of asthma
- have aseptic meningitis or other connective tissue diseases such as SLE (Systemic Lupus Erythematosus)
- have a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) or suffer from bowel problems.
- have kidney or liver problems
- are elderly, as it increases the frequency of adverse reactions
- are in the first 6 months of pregnancy
- experience prolonged bleeding time

There is a risk of kidney problems in dehydrated children and adolescents.

**Other important information**

**Risk of heart attack or stroke:**

Anti-inflammatory/pain-killer 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.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 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 of 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.

**Women of childbearing age:**

Ibuprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

**Other medicines and Ibuprofen Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ibuprofen may affect or be affected by some other medicines. For example:

- other painkillers, including non-steroidal anti-inflammatory medicines e.g. indometacin or diclofenac, and COX-2 inhibitors e.g. celecoxib

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- diuretics e.g. furosemide (drugs to increase urine output)
- corticosteroids (used to treat inflammatory conditions)
- methotrexate (used to reduce inflammation)
- lithium (used as a mood stabilizer)
- zidovudine (used in retroviral disease like HIV)
- selective serotonin reuptake inhibitors (SSRIs), e.g. fluoxetine (used for depression)
- ciclosporin or tacrolimus (given after transplant surgery, or used in psoriasis or rheumatism)
- mifepristone (for termination of pregnancy)-do not take ibuprofen if you have taken mifepristone in the last 12 days
- quinolone antibiotics e.g. ciprofloxacin (for infections)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan) or drugs for heart disease or to stimulate your heart e.g. glycosides such as digoxin
- cholestyramine
- sulphonyl ureas such as glibenclamide (to treat diabetes)
- aminoglycosides (a type of antibiotic)
- voriconazole or fluconazole (types of anti-fungal drugs)
- Ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen)

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 other medicines.

**Pregnancy, breast-feeding and fertility**

- Do **NOT** take this medicine if you are in the last 3 months of pregnancy.
- Speak to your doctor or pharmacist before taking this medicine if you are in the first 6 months of pregnancy, are breast feeding or are planning to breastfeed.
- Always ask your doctor or pharmacist for advice before taking any other medicine.

**Ibuprofen Tablets contain Lactose and Sucrose**

- If you have been told by your doctor that you have intolerance to some sugars, check with your doctor before taking this medicine as it contains **LACTOSE** and **SUCROSE**.

### 3. How to take Ibuprofen tablets

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.
- The tablets should be swallowed with a drink of water.
- Take with or after food to reduce the possibility of side effects

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#### Adults, the elderly and adolescents of 12 to 17 years:

- Take one tablet up to 3 times a day.
- Leave at least 4 hours between doses.
- Do not take more than 3 tablets in any 24 hour period.

This product is intended for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

**Adults and the elderly:** If this medicinal product is required for more than 10 days, or if symptoms persist or worsen, consult your doctor.

**Adolescents:** If this medicinal product is required for more than 3 days, or if symptoms persist or worsen, consult your doctor.

**Do not give to children under 12 years of age.**

**DO NOT EXCEED THE STATED DOSE.**

#### If you take more Ibuprofen Tablets than you should

If you have taken more Ibuprofen than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of 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.

#### If you forget to take a dose of Ibuprofen Tablets

If necessary, take the missed dose when you remember.

**DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine may sometimes cause side effects, although not everybody gets them.

**If you experience any of the following serious effects then STOP taking this medicine immediately and contact your doctor or pharmacist:**

- Peptic ulceration or perforation. Symptoms could include severe abdominal pain, vomiting blood (or liquid with what looks like coffee grounds), blood in the faeces (stools/motions) or passing black tarry stools
- Inflammation of the brain lining. Symptoms could include stiff neck, headache, feeling or being sick, fever or feeling disorientated
- Severe allergic reactions. Symptoms could include fainting, faster heart rate, swelling of the face, tongue and throat
- Worsening of asthma and wheezing or difficulty breathing

- Severe forms of skin reactions including peeling and blistering of the skin, mouth and genitals (Stevens Johnson syndrome, erythema multiforme and toxic epidermal necrolysis)
- 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).

#### Other possible side effects

##### Uncommon (may affect up to 1 in 100 people)

- Allergic reactions such as hives, skin rashes and itching (or SLE)
- Abdominal pain, indigestion, heartburn and feeling sick
- Headache

##### Rare (may affect up to 1 in 1,000 people)

- Diarrhoea, wind, constipation or being sick

##### Very rare (may affect up to 1 in 10,000 people)

- Reduction in blood cells, which can make the skin pale or yellow, cause fever, sore throat, mild mouth ulcers, flu-like symptoms, exhaustion or weakness, easy bruising, or bleeding from the skin or nose
- High blood pressure, heart failure or chest pain
- Nervousness, visual disturbance, ringing in the ears and dizziness
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes
- Kidney problems. Symptoms could include swelling of the ankles

##### Not Known (frequency cannot be estimated from the available data)

- Skin eruptions

Medicines such as Ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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.

### 5. How to store Ibuprofen Tablets

- Keep this medicine out of the sight and reach of children.
- Blisters: Do not store above 25°C. Store in the original package. Containers: Do not store above 25°C. Keep the container tightly closed.
- Do not use this medicine after the expiry date (EXP.) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Ibuprofen Tablets contain

- The active substance is Ibuprofen.
- Other ingredients are: lactose, potato starch, hypromellose, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate, sucrose, talc, titanium dioxide (E171), maize starch, pregelatinised starch

#### What Ibuprofen Tablets look like and the contents of the pack

- The tablets are white sugar coated.
- The tablets are available in packs containing 6, 12, 24, 25, 48, 84, 96 or 250 tablets.
- Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Limited,  
Unit 3 Canalside, Northbridge Road, Berkhamsted,  
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**Ibuprofen 400mg Tablets; PL 17907/0079**

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