

FLAT DIMENSION = 185 x 560mm
FOLDED DIMENSION = 185 x 35mm

30mm

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Package leaflet: Information for the user

IBUPROFEN 200MG TABLETS

Ibuprofen

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, pharmacist or nurse 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, pharmacist or nurse. 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 is Ibuprofen Tablets is and what it is 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 is Ibuprofen Tablets is and what it is used for

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

These tablets are used for the relief of rheumatic or muscular pain, backache, neuralgia, migraine, headache, dental pain, period pains, feverishness, and the symptoms of cold and influenza.

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

Do not take Ibuprofen 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
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have had 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 in the last 3 months of pregnancy
- are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take this medicine
- have a condition which increases your tendency to bleeding.

Warnings and Precautions

Talk to your doctor or pharmacist or nurse before taking Ibuprofen Tablets if you:

- suffer from asthma, or have a past history of asthma
- have aseptic meningitis or other connective tissue diseases as Systemic Lupus Erythematosus (SLE - a condition of the immune system causing joint pain skin changes and other organ disorders)
- have a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) or suffer from bowel problems
- are in the first 6 months of pregnancy
- have kidney, heart or liver problems
- are elderly, as it increases the frequency of adverse reactions
- experience prolonged bleeding time
- have high cholesterol or previously have had a heart attack or stroke
- are a smoker
- you have an infection - please see heading "Infections" below.
- If you are taking Ibuprofen 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 4).
- 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 immediately Ibuprofen Tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

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

Take special care with this medicine:

Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Ibuprofen Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections

Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 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 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.

Female Fertility

Ibuprofen belongs to a group of medicines which may affect fertility in women. Fertility goes back to normal when you stop taking the

medicine. It is unlikely that if you only take Ibuprofen occasionally it will affect your chances of becoming pregnant. If you have problems becoming pregnant talk to your doctor before taking this medicine.

There is a risk of renal impairment in dehydrated children and adolescents.

If you are taking this medicine for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Low dose Aspirin

Do not take Ibuprofen if you are taking more than 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before you take Ibuprofen.

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/acetysalicylic 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

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- Do not take Ibuprofen 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 ibuprofen 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, ibuprofen 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.

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Ibuprofen Tablets contain Sucrose

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content:

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

3. How to take Ibuprofen Tablets

- Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse 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.

This medicine is for short term use only.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Adults, the elderly and children and adolescents between 12 to 18 years:

- Take one or two tablets up to 3 times a day.
- The dose should not be repeated more frequently than every 4 hours.
- Do not take more than 6 tablets in any 24 hour period.

In children and adolescents between 12 to 18 years:

If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms persist or worsen, consult your doctor.

In adults:

Do not take for longer than 10 days unless your doctor tells you to.

If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

Do not give to children under 12 years of age.

If you do not get better, or get worse, talk to your doctor. They will tell you if it is safe to carry on taking the medicine.

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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

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. 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- 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
- 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].
- 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).
- Ibuprofen, 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 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness, light-headedness.
- 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 using Ibuprofen if you develop these symptoms and seek medical attention immediately. See also section 2.

Other possible side effects

Uncommon (may affect up to 1 in 100 people)

- Allergic reactions such as hives, skin rashes and itching
- 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
- Nervousness, visual disturbance, ringing in the ears and dizziness
- Liver problems. Symptoms could include yellowing of the skin or the whites of the eyes
- 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)
- Kidney problems. Symptoms could include passing less or more urine, cloudy urine or blood in urine, pain in the back and/or swelling (particularly in the legs)

- Drop in blood pressure or irregular heart beat

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

- Skin eruptions
- skin becomes sensitive to light
- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- worsening of colitis and Crohn’s disease
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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, pharmacist or nurse. 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 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.
- Do not store above 25°C. Store in the original package in order to protect the tablets from moisture and light.
- 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: sucrose, microcrystalline cellulose, potato starch, sodium starch glycolate, povidone, alginic acid, colloidal anhydrous silica, purified talc, magnesium stearate, PVAP sealcote (contains polyvinyl acetate phthalate & stearic acid), croscarmellose sodium, sodium lauryl sulfate, titanium dioxide (E171), calcium carbonate, acacia and carnauba wax.

What Ibuprofen Tablets look like and contents of the pack

- The tablets are round white, sugar-coated.
- The tablets are available in packs containing 8, 12 and 16 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,

Unit 3, Canal side, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom

Telephone: 0044 (0)1442 200922

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