

PACKAGE LEAFLET: INFORMATION FOR THE USER**IBUPROFEN TABLETS BP 600 MG**
Ibuprofen

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

1. What 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 Ibuprofen Tablets is and what it is used for

Ibuprofen Tablets belong to a group of medicines called non-steroidal anti-inflammatory drugs. They can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Ibuprofen Tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

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)
- suffer from asthma or have ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers.
- 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

Warning and Precautions

Talk to your doctor, pharmacist or nurse if you:

- have poor circulation in the legs (peripheral arterial disease)
- 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 had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-inflammatory Drugs)

- 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 kidney or liver problems
- have a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) or suffer from bowel problems
- are elderly, as it increases the frequency of adverse reactions
- 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).

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

Take special care with this medicine:

- 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.

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 think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).

Women of childbearing age:

Ibuprofen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or 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. ibuprofen, 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 stabiliser)
- zidovudine (used in retroviral disease like HIV)
- selective serotonin reuptake inhibitors (SSRIs) e.g. fluoxetine (used for depression)
- cholestyramine (a drug used to lower cholesterol)
- 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)
- 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 known as sulphonylureas such as glibenclamide (used to treat diabetes)
- aminoglycosides (a type of antibiotic)
- 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 cardiac glycosides, such as digoxin used to treat heart conditions.
- Alcohol: Ibuprofen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Ibuprofen might make these side effects worse.

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.

Driving and operating machinery

- These tablets may cause dizziness, drowsiness, fatigue and visual disturbance. If affected do not drive or operate machines.

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 advised by your doctor or pharmacist has told you.
- You should 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.
- Ibuprofen tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

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:

- Take one tablet initially, followed by one tablet every 6 hours if necessary.

- Do not take more than 4 tablets in any 24 hour period.

Elderly:

Your doctor may have prescribed a slightly different dose to the usual dose stated above; you should always follow your doctor's instructions for taking medicines.

Children: The usual daily dosage is 20mg per kg of body weight, given in divided doses. Ibuprofen tablets should not be taken by children weighing less than 7 kg. In cases of severe juvenile arthritis your doctor may increase the dosage up to 40mg/kg in divided doses.

Do not exceed the recommended dose or duration of treatment (2 days). If symptoms persist consult your doctor.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine. This risk may be increased if you are dehydrated. The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Ibuprofen. Tell your doctor if you have been having headaches while taking this 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 cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

If you suffer from any of the following at any time during your treatment STOP TAKING Ibuprofen Tablets and *seek immediate medical help*:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Liver, kidney problems or difficulty urinating

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.

TELL YOUR DOCTOR AND STOP TAKING THE TABLETS IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- 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.

Medicines such as Ibuprofen Tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Ibuprofen Tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders such as reduction in blood cells and platelet counts - the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin. Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure. Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen. Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (affects up to 1 in 10 people):

- feeling dizzy or tired
- diarrhoea, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (affects up to 1 in a 100 people):

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- mouth ulcers
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)

Rare (affects up to 1 in a 1000 people):

- feeling depressed or confused

Very rare (affects up to 1 in 10,000 people):

- inflammation of the pancreas

Not known (cannot be estimated from the available data):

- skin becomes sensitive to light
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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
- Blisters: Do not store above 25°C. Store in the original package. Containers: Do not store above 25°C. Store in the original container. 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 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
- The other ingredients are: maize starch, microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide, alginate acid, sodium lauryl sulfate, sodium starch glycolate, magnesium stearate, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyethylene glycol 400, erythrosine aluminium lake (E127) and titanium dioxide (E171).

What Ibuprofen Tablets look like and contents of the pack

- Ibuprofen Tablets are pink coloured capsule shaped film coated tablets.
- They are available in packs of 50, 56, 84, 100, 250 or 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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