

Artwork For Submission



Package leaflet: information for the user  
Ibuprofen 600 mg film-coated tablets  
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Ibuprofen belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). Ibuprofen relieves pain and has an anti-inflammatory effect.

Ibuprofen is used for pain of mild to moderate intensity such as period pain, toothache, pain after operations and headache, including migraine. Ibuprofen can also be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still’s disease), other types of arthritis, ankylosing spondylitis, frozen shoulder, bursitis, tendonitis, tenosynovitis, lower back pain, sprains and strains.

Ibuprofen is used by adults and adolescents (12-18 years old, 40 kg and above).

2 What you need to know before you take Ibuprofen Tablets

Do not take Ibuprofen Tablets if you:

- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section
- are in the last three months of pregnancy
- have an increased tendency to bleed
- have severe liver and kidney disease
- have severe heart failure
- have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers or stomach bleeding in the past
- have ever had bleeding or a tear in your stomach or gut when taking NSAIDs
- have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, itchy rash, swelling) to ibuprofen, acetylsalicylic acid (aspirin) or other NSAIDs.

Warnings and precautions

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 and contact immediately your doctor or medical emergencies if you notice any of these signs.

Talk to your doctor or pharmacist before taking Ibuprofen Tablets:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Ibuprofen tablets 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.
- Are you sensitive (allergic) to any of the ingredients in the tablets? These are listed in Section 6.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint? Do not take Ibuprofen Tablets if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen Tablets if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries).
- have any kind of stroke or 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).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Have you been told by your doctor that you have an intolerance to some sugars?
- Are you or your child dehydrated? As there is a risk of kidney damage in dehydrated children adolescents and the elderly.
- If you are taking ibuprofen 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 4).

- If you have an infection - please see heading ‘Infections’.

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 taking Ibuprofen and seek medical attention immediately, if you notice any skin of the symptoms related to 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 section 4.

Infections

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

Can you take Ibuprofen Tablets with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/ prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with other medicines. In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- diuretics (water tablets)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

**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.

**Pregnancy and breast-feeding:** The use of Ibuprofen whilst pregnant or breast feeding should be avoided. 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.Ibuprofen should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

**Driving and Using Machines:** Ibuprofen may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Ibuprofen tablets contains lactose

This medicinal product contains a type of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per capsule, i.e. essentially ‘sodium free’.

3 How to take Ibuprofen Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

*The recommended dose for adults and adolescents (12-18 years old, 40 kg and above)*

The usual dosage is one 600 mg tablet 1-3 times daily. Your doctor may choose to increase this depending on what you are being treated for; but no more than 4 tablets (2400 mg) should be taken in one day.

The lowest effective dose should be used for the shortest



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duration necessary to relieve symptoms.

To help prevent a burning sensation in the throat or mouth, swallow the tablets whole with at least half a glass of water.

Take ibuprofen preferably with or after food, especially if you have a sensitive stomach. If you take ibuprofen shortly after eating, the onset of action may be delayed.

If you have severe liver and kidney disease or are elderly your doctor will tell you the correct dose to take which will be the lowest dose possible.

The tablet cannot be divided into equal doses.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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

If you have taken more tablets 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 occur 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 furthermore be low blood pressure and reduced breathing.

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 forget to take Ibuprofen**

Do not use 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, ibuprofen tablets can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following:

- Liver, kidney problems or difficulty urinating
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Ibuprofen 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 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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.

STOP TAKING Ibuprofen Tablets and seek immediate medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- Signs of intestinal bleeding such as
- Passing blood in your faeces (stools/motions)
- Passing black tarry stools
- Vomiting any blood or dark particles that look like coffee grounds
- 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. Symptoms of DRESS include widespread skin rash, high body temperature, enlarged lymph nodes and an increase of eosinophils (a type of white blood cells).
- 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).

**TELL YOUR DOCTOR AND STOP TAKING IBUPROFEN 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).
- Severe spreading skin rash (‘Stevens-Johnson Syndrome’, ‘toxic epidermal necrolysis’ and ‘erythema multiforme’, symptoms include severe skin rash, blistering of skin, including inside mouth, nose,

and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)

- 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).

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
- skin becomes sensitive to light
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- 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)
- mouth ulcers

**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):**

- 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 Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

**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 at: [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.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle, blister or carton, after EXP.

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 contains**

Each film-coated tablet contains 600 mg ibuprofen

The active substance is ibuprofen.

The other ingredients are

*Tablet Core:*

Colloidal silicon dioxide, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, magnesium stearate

*Tablet Coating:*

Opadry II White contains; hypromellose, titanium dioxide, lactose monohydrate, macrogol 4000, Sodium citrate

**What Ibuprofen Tablets looks like and contents of the pack**

White coloured oval shaped biconvex film coated tablets debossed ‘6’ on one side and break line on other side.

Dimension of the tablet: Length- 17.70 mm±0.20 mm and width - 10.60 mm±0.20 mm.

Ibuprofen 600 mg: 60 and 100 film-coated tablets in PVC-Aluminium blisters

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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