

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ibuprofen 400 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 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 NSAIDs (non-steroidal anti-inflammatory drugs). Ibuprofen tablets reduce fever, relieve pain and have an anti-inflammatory effect.

In adults and children over 12 years (>40 kg): Short term treatment of fever and pain of mild to moderate intensity, including dysmenorrhea.

Long term symptomatic treatment of pain and inflammation in chronic inflammatory rheumatic diseases.

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

Do not take Ibuprofen tablets:

- if you are allergic (hypersensitive) to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- if you are in the last three months of pregnancy.
- if you have an increased tendency to bleed.
- if you previously have had bleeding or perforation in your stomach or intestine when treated with Ibuprofen tablets or a similar product (other NSAIDs).
- if you have severe liver and kidney disease.
- if you have severe heart failure or coronary heart disease.
- if you have a stomach ulcer, duodenal ulcer, or if you have had a stomach ulcer or duodenal ulcer previously when treated with ibuprofen or a similar product.
- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, rash) to acetylsalicylic acid or other anti-inflammatory drugs.
- If you are suffering from bleeding on the brain (cerebrovascular bleeding) or other active bleeding.
- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).

Warnings and precautions:

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 tablets 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.

- Always aim for the lowest possible dose and shortest possible treatment time to reduce the risk of side effects. It is generally the case that higher than recommended doses can entail risks. This also means that the combination of several NSAID products at the same administration time should be avoided.

If you use painkillers for a long time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor or pharmacist.

- have asthma, chronic rhinitis (chronic stuffy and runny nose) or allergic diseases since Ibuprofen tablets can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions.
- People who have or have had the following illnesses or symptoms should consult a doctor before starting treatment with Ibuprofen tablets: systemic lupus erythematosus (connective tissue disease), impaired kidney or liver function, mild to moderate heart failure, asthma, inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed.
- Like other anti-inflammatory drugs, Ibuprofen tablets can mask signs of infection.
- This product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.
- Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of treatment.
Treatment must be stopped and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with Ibuprofen tablets (see Section 4).
- In patients with Systemic lupus erythematosus and mixed connective tissue disorders, conditions of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs as there may be an increased risk of aseptic meningitis.
- Stop taking Ibuprofen tablets and contact a doctor immediately if you develop any of the following symptoms (angioedema)
 - swelling of the face, tongue or throat,
 - difficulties swallowing,
 - hives and difficulties breathing.
- Medicines like Ibuprofen tablets may entail a slightly increased risk of heart attack or stroke. This increased risk is more likely when using high doses and in long-term treatment. Do not exceed the recommended dose or treatment time.

- Consult a doctor or pharmacist about your treatment if you have heart problems, if you previously have had a stroke or if you think that you have an increased risk for these conditions (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you smoke).
- Do not take Ibuprofen tablets if you are planning a pregnancy. Consult your doctor first.
- During varicella it is advisable to avoid use of this drug.
- Ibuprofen tablets may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.
- If you have been told by your doctor that you have intolerance to some sugars.
- 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.
- you have an infection - please see heading “Infections” below.

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.

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.

Elderly

Elderly patients should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.

Children and adolescents

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

Other medicines and Ibuprofen tablets:

Do not use different types of pain-relieving medicines at the same time unless directed by a doctor.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

- tumours and immune system disorders (methotrexate, tacrolimus, ciclosporin, pemetrexed),
- manic depressive illness (lithium),
- irregular heart beat (digoxin),
- pain (acetylsalicylic acid),

- thromboembolic disorders (medicines that are anti-coagulants, i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine, dicumarol),
- depression (medicines called SSRIs – selective serotonin reuptake inhibitors),
- high blood pressure (medicines that reduce high blood pressure, ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan, diuretics),
- rejection in patients receiving organ transplants (medicines that suppress your immune system, such as ciclosporin or tacrolimus),
- inflammation (corticosteroids).
- fungal infections (antifungals particularly voriconazole or fluconazole)
- diabetes mellitus (sulphonylureas)
- human immunodeficiency virus (HIV) infection (zidovudine, ritonavir)
- antibiotic (quinolones such as ciprofloxacin)
- aminoglycosides (a type of antibiotic)
- mifepristone
- probenecid
- any other ibuprofen preparations, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including acetylsalicylic acid
- cholestyramine (a drug used to lower cholesterol)
- Ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

For this reason, the doctor treating you needs to know about all the medicines you are taking.

Some other medicines may also affect or be affected by the treatment of Ibuprofen tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen tablets with other medicines.

Ibuprofen tablets with food and drink

Ibuprofen tablets could be used together with food and drinks. Ibuprofen tablets can be given on an empty stomach for faster relief. If Ibuprofen tablets are taken together with alcohol, side effects may be increased.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take ibuprofen tablets 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 tablets 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 tablets 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

Ibuprofen tablets passes into breast milk. The use of Ibuprofen tablets is therefore not recommended while breast-feeding. However, consult a doctor if using Ibuprofen tablets more than occasionally while breast-feeding is required.

Fertility

The use of Ibuprofen tablets may affect fertility. The use of Ibuprofen tablets is not recommended while attempting to conceive or during investigation of infertility.

Driving and using machines

Ibuprofen tablets may impair reactions in some people. Undesirable effects such as dizziness, drowsiness and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery. This should be taken into consideration on occasions when high alertness is required, e.g. driving, and applies to a greater extent in combination with alcohol.

Ibuprofen tablets contain lactose monohydrate and sodium

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

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 Ibuprofen tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Take your ibuprofen tablets with or after food, with plenty of fluid. Ibuprofen tablets should be swallowed whole and not chewed, broken, crushed or sucked on to avoid oral discomfort and throat irritation.

Rheumatic diseases

- initial treatment: 2x400 mg tablets, three times daily, i.e. 2400 mg per day
- maintenance treatment: 1x400 mg tablets, three to four times daily, i.e. 1200 to 1600 mg per day.

An interval of at least 4-6 hours should be allowed between doses. The total daily dose must not exceed 2400mg in divided doses. Some patients can be maintained on 600 – 1200mg daily.

Juvenile Rheumatoid Arthritis

For Juvenile Rheumatoid Arthritis, the recommended dose is 20mg-30mg/kg body weight daily in 3 to 4 divided doses up to a maximum of 40mg/kg body weight daily in severe cases. In children weighing less than 40 kg, use of a different strength or a liquid formulation of ibuprofen should be considered to aid accurate dosing.

Short term symptomatic treatment of fever and pain of mild to moderate intensity:

Adults and adolescents over 12 years (>40 kg)

One 400 mg tablet one to four times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Single doses exceeding 400 mg have not been shown to have any additional analgesic effect. The 400 mg tablet should only be used for more intense pain or fever that are not relieved by a 200 mg ibuprofen tablet.

Dysmenorrhoea

One 400 mg tablet one to three times daily, as needed. An interval of at least 4-6 hours should be allowed between doses. Treatment is started at the first sign of menstruation problems.

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 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).

If you take more Ibuprofen tablets than you should

If you have taken more Ibuprofen 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 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 Ibuprofen tablets

Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Stop taking Ibuprofen tablets and contact a doctor immediately if you develop any of the following symptoms

- signs of angioedema such as
 - swelling of the face, tongue or throat,
 - difficulties swallowing,
 - hives and difficulties breathing.
- 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 very rare side effect).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome (frequency not known).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome) (frequency not known).
- 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) (frequency not known).

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).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).

Medicines such as Ibuprofen tablets have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

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

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen.

Very rarely Ibuprofen tablets may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Ibuprofen tablets have also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (may affect up to 1 in 10 people):

- Headache, lightheadedness.
- Gastrointestinal side effects (indigestion, diarrhoea, nausea, vomiting, abdominal pain, flatulence, constipation, black stools, bleeding in stomach and intestine, vomiting blood).
- Rash.
- Tiredness.

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

- Rhinitis.
- Hypersensitivity.
- Insomnia, anxiety
- Visual disturbances, hearing impairment.
- Difficulty breathing, bronchial spasm, asthma.
- Mouth ulceration. Stomach ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach.
- Hepatitis. Jaundice. Abnormal liver function.
- Hives, itching, small bruises in skin and mucous membranes.
- Photosensitivity.
- Impaired kidney function.
- Changes in blood count.
- Drowsiness.
- Tingling sensation.
- Hearing loss.
- Anaemia (a reduction in red blood cells or hemoglobin, which can make the skin pale and may lead to weakness).

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

- Non-bacterial meningitis.
- Allergic reaction.
- Depression, confusion.
- Impaired vision, dizziness
- Liver damage and fluid retention in body.
- Tinnitus (ringing in ears) and vertigo.

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

- Inflammation of the pancreas, liver failure.
- Skin and mucous membrane changes (sometimes severe) such as epidermal necrolysis and/or erythema multiforme.

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

- Exacerbation of Colitis and Crohn's Disease.
- Cardiac failure.

- Myocardial infarction.
- Hypertension.

Please note that Ibuprofen tablets can prolong bleeding time.

There have been reports of high blood pressure and heart failure as well as worsening of ulcers in the large intestine and Crohn's disease (inflammatory bowel disease) in treatment with pain-relieving medicines (NSAIDs).

Exceptional serious infections of the skin in case of varicella. Exacerbation of infection-related inflammations (e.g. development of necrotising fasciitis) coinciding with the use of NSAIDs has been described.

Medicines like Ibuprofen tablets may entail a slightly increased risk of heart attack 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 HPRRA Pharmacovigilance
Website: www.hpra.ie

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 blister or 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.
Each film-coated tablet contains 400 mg ibuprofen

The other ingredients are:

Tablet core:

Lactose monohydrate, maize starch, croscarmellose sodium, colloidal anhydrous silica, microcrystalline cellulose, magnesium stearate.

Tablet coating:

Polyvinyl Alcohol (E1203), Titanium Dioxide (E171), Macrogol/PEG 3350 (E1521), Talc, Erythrosine Aluminium lake (E127).

What Ibuprofen tablets look like and contents of the pack

Ibuprofen 400 mg film-coated tablets are pink coloured, round, approximately 13 mm in diameter, biconvex film coated tablets debossed with 'DK' on one side and plain on other side.

Ibuprofen 400 mg tablets are packaged in PVC - Aluminium blisters or PVC/PVdC – Aluminium Blisters.

Pack sizes: 10, 12, 14, 20, 21, 24, 28, 30, 40, 42, 48, 50, 60, 84, 100 or 500 film-coated tablets in carton.

Not all pack sizes may be marketed.

Marketing Authorisation holder

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicine
United Kingdom (Northern Ireland)	Ibuprofen 200/400/600 mg Film-coated Tablets
Austria	Ibuprofen Accord 400/600 mg Filmtabletten
Bulgaria	Ibuprofen Акорд 200/400/600 мг филмирани таблетки
Estonia	Ibuprofen Accord
Finland	Ibuprofen Accord 400/600 mg tabletti, kalvopäällysteinen
Ireland	Ibuprofen 200/400/600 mg Film-coated Tablets
Italy	Ibuprofene Accord
Malta	Ibuprofen 200/400/600 mg Film-coated Tablets
Netherland	Ibuprofen Accord 200/400/600 mg Filmomhulde tabletten
Sweden	Ibuprofen Accord 200/400 mg filmdragerade tabletter
France	Ibuprofene Accord 200/400 mg, comprimés pelliculés

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