

Ibuprofen 400mg , 600mg film-coated tablets

What is Ibuprofen and what is it used for?

Ibuprofen belongs to the group of anti-inflammatory painkillers. The active ingredient, Ibuprofen, has anti-inflammatory, pain-relieving, and fever-reducing properties. Ibuprofen 400 mg, film-coated tablets and Ibuprofen 600 mg, film-coated tablets are used in the treatment of:

- Situations where pain is the main symptom, such as headache, toothache, muscle pain, menstrual pain, rheumatic pain, pain after dental or other oral surgery, pain after an operation, pain and fever associated with flu and cold or after vaccination.
- Various joint and spinal conditions such as joint inflammation (rheumatoid arthritis), joint diseases caused by wear and tear (osteoarthritis), and ankylosing spondylitis.
- Various muscle, tendon, and ligament conditions such as tendonitis, tenosynovitis, and bursitis.

When should you not use this medicine or be extra careful?

When should you not use this medicine?

- If you are allergic (hypersensitive) to Ibuprofen or any of the other ingredients of the tablet, or to other anti-inflammatory agents (such as aspirin, diclofenac, indomethacin). This may have manifested itself in asthma attacks, nasal congestion, or skin rash with or without itching and hives after taking these products.
- If you have or have had a stomach ulcer or bleeding at least twice.
- If you have ever had bleeding or perforation in your stomach or intestines after using NSAID drugs.
- In case of cerebral haemorrhage.
- In case of severe kidney and/or liver impairment.
- When using anticoagulants simultaneously.
- In case of predisposition to bleeding.
- In case of severe heart failure.
- During the last three months of pregnancy.

When should you be extra careful with this medication?

Contact your pharmacist or doctor if:

- you have had a stomach ulcer or duodenal ulcer in the past;
- in elderly patients (this group of patients is generally more sensitive to the side effects of ibuprofen);
- in patients with blood clotting disorders (ibuprofen can inhibit blood clotting at high doses);
- in patients with a poorly functioning liver or kidneys (usually your doctor will adjust the dosage);
- in patients with high blood pressure and/or heart disease (ibuprofen can retain fluid);
- if you have gastrointestinal disorders (including ulcerative colitis or Crohn's disease) or have had them in the past;
- if you have chickenpox (varicella) - it is advisable to avoid using this medication;
- if you are taking other NSAIDs. Concurrent use with NSAIDs, including specific cyclooxygenase-2 inhibitors, increases the risk of side effects (see section "Are you taking any other medicines?" below) and should be avoided.

If there is bleeding in the stool (recognizable by ink-black foul-smelling stool), ibuprofen should be discontinued immediately and the doctor should be consulted. Bleeding in the stool indicates a gastrointestinal bleeding!

If the doctor has detected an abnormality in your blood count or a significant liver dysfunction, ibuprofen should be discontinued.

Due to the anti-inflammatory action of ibuprofen, typical signs of inflammation such as pain, swelling, fever, and redness can be suppressed, so an infection is less noticeable. Therefore, the use of tablets is not recommended in patients with an infection.

Side effects can be minimized by using the minimal effective dose for the shortest possible time.

Anti-inflammatory/pain relievers such as ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly at high doses. You should not exceed the recommended dose or duration of treatment.

Discuss your treatment with your doctor or pharmacist before taking this medication if you: have heart problems, including heart failure, angina (chest pain), or if you have had a heart attack, a bypass operation, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or a stroke (including 'mini-stroke' or transient ischemic attack 'TIA'). If you have high blood pressure, diabetes, or high cholesterol, have a family history of heart problems or stroke, or if you smoke. If you have an infection - see the "Infections" section below.

Ibuprofen 400 mg film-coated tablets and Ibuprofen 600 mg film-coated tablets can mask symptoms of infections, such as fever and pain. Therefore, it is possible that Ibuprofen 400/600 mg, film-coated tablets may delay appropriate treatment of an infection, which can lead to an increased risk of complications. This has been observed in bacterial pneumonia and bacterial skin infections that can occur with chickenpox. If you use this medication while you have an infection, and the symptoms of your infection persist or worsen, you should consult a doctor immediately.

If you have heart problems, have had a stroke, or believe you may be at risk for these conditions (for example, if you have high blood pressure, diabetes, or high cholesterol levels or if you smoke), you should discuss this with your doctor or pharmacist before taking this medication.

Severe skin reactions have been reported with the use of this medication. Stop taking this medication and seek medical help immediately if you experience skin rash, damage (lesions) to mucous membranes, blisters, or other allergic reactions. These may be the first symptoms of a very serious skin reaction.

Do you still use other medications?

Tell your doctor or pharmacist if you are using or have recently used other medications, including those available without a prescription.

Inform your doctor if you are using or plan to use any of the following medications concurrently with ibuprofen:

- Diuretics (water pills): ibuprofen can reduce the blood pressure-lowering effect of these medications;
- Anticoagulants: ibuprofen can enhance the effects of these medications at high doses, so inform your thrombosis service about your use of ibuprofen;
- Beta blockers (a group of medications used for high blood pressure, chest pain, and arrhythmia): ibuprofen can reduce the blood pressure-lowering effect of these medications;
- Strong anti-inflammatory medications (called corticosteroids, such as prednisone and prednisolone): because the risk of gastrointestinal bleeding may increase;
- Digoxin (a medication used for poor heart function), phenytoin (a medication used for epilepsy), and lithium (a medication used for depression): in rare cases, ibuprofen may enhance the effects and/or side effects of these medications;
- Platelet inhibitors because the risk of gastrointestinal bleeding may increase;
- Selective serotonin reuptake inhibitors (medications for depression) - because the risk of gastrointestinal bleeding may increase;
- If you use low-dose aspirin.

What medications should you avoid taking while using this medication?

Ibuprofen 400/600 mg, film-coated tablets may affect or be affected by other medications:

- Medications that are anticoagulants (i.e. blood thinners/prevention of blood clotting, such as aspirin/acetysalicylic acid, warfarin, and ticlopidine);
- Medications that lower high blood pressure (ACE inhibitors such as captopril; beta blockers such as atenolol; angiotensin II receptor antagonists such as losartan).

Some other medications may also affect or be affected by treatment with Ibuprofen 400/600 mg. Therefore, always consult a doctor or pharmacist before using Ibuprofen 400/600 mg, concurrently with other medications.

Pregnancy, breastfeeding, and fertility

Ask your doctor or pharmacist for advice before taking any medication.

Pregnancy

The use of ibuprofen during pregnancy, especially during the last months, is strongly discouraged. If you become pregnant while using ibuprofen, consult your doctor.

Breastfeeding

Ibuprofen passes into breast milk in very small amounts and is unlikely to affect the infant unless the infant is allergic to ibuprofen.

Use ibuprofen during the breastfeeding period only in consultation with your doctor.

Fertility

This product belongs to a group of medications (NSAIDs) that can adversely affect women's fertility with use. This is reversible by discontinuing the use of this medication.

Driving and operating machinery

If you experience dizziness while using ibuprofen, do not drive a car or operate machinery.

Ibuprofen contains lactose; If your doctor has told you that you are intolerant to certain sugars, contact your doctor before taking this medication. Long-term use of any type of pain reliever for headaches can worsen the headache. If this situation occurs or is suspected, a doctor should be consulted and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who frequently or daily experience headaches despite (or due to) regular use of headache medication. There is a risk of kidney dysfunction in adolescents who are dehydrated. The risk of side effects is minimized by using the lowest effective dose for the shortest possible time. If symptoms persist for more than 14 days, consult your doctor.

How do you use this medication?

The lowest effective dose should be used for the shortest period necessary to relieve symptoms. If you have an infection, consult a doctor immediately if symptoms (such as fever and pain) persist or worsen.

Adolescents (12-18 years old): If this medicine needs to be used for more than 3 days by adolescents, or if symptoms worsen, a doctor should be consulted.

Dosage: Usual dosage for adults and children over 12 years old: Rheumatism, joint wear (osteoarthritis) and Bechterew's disease: The usual dosage is 1200 to 1600 mg per day. The daily dose is divided into 3 or 4 intakes. In severe cases, a maximum of 2400 mg per day can be given temporarily.

Muscle disorders, muscle attachments, tendons, pain after surgery and menstrual pain: The recommended starting dose is 1200 mg per day. The daily dose is divided into 3 or 4 intakes. In severe cases, the dosage can be increased to 1600 mg per day.

In dental procedures, it is advisable to administer the first dose before the procedure.

Fever and pain in flu and colds, or after vaccination and various other forms of pain: The recommended starting dose is 400 mg, followed by 200-400 mg each time every 4 to 6 hours if necessary. The maximum dose is 1200 mg per day.

Doses of 200 mg each with these tablets are not possible.

Side effects can be minimized by using the minimal effective dose for the shortest possible time. If you have an infection, consult a doctor immediately if symptoms (such as fever and pain) persist or worsen.

Method of use

Rheumatoid patients who suffer from morning stiffness can take the first dose immediately after waking up with some tea or another drink. The active ingredient is then absorbed quickly, relieving pain and stiffness quickly.

- The following doses should be taken after meals.
Take the tablets with half a glass of water.

What to do if you have used more ibuprofen than you should

If you have taken more Ibuprofen 400 mg, film-coated tablets or Ibuprofen 600 mg, film-coated tablets than allowed, or if a child has accidentally taken this medicine, go immediately to your doctor or the nearest emergency department and take the packaging of your medicine and this leaflet with you.

Keep the packaging so that the doctor can see which medicine it is.

Overdosing can cause: nausea, abdominal pain, stomach pain, vomiting (may be blood vomiting), dizziness, double vision, confusion, and tremors in eye movements, headache, and tinnitus.

In severe cases, low blood pressure, poorly functioning kidneys, and coma may occur. At high doses, drowsiness, chest pain, palpitations, reduced consciousness, seizures with convulsions (especially in children), weakness and dizziness, blood in urine, cold body feel, and breathing problems have been reported.

What to do if you forgot to use Ibuprofen

If you forget a dose, take it as soon as possible unless it is almost time for the next dose. In the latter case, do not take the missed dose and continue with the original dosing schedule. Never double the dose on your own! If in doubt, consult your doctor or pharmacist. If you stop using Ibuprofen. Never stop using Ibuprofen on your own, always consult your doctor first. The pain-relieving and anti-inflammatory effects of Ibuprofen may decrease after a few days, so your original symptoms may recur. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

Possible side effects

Like all medicines, Ibuprofen can cause side effects, although not everyone gets them.

The frequency of side effects is classified as follows:

Common: affects more than 1 in 100, but less than 1 in 10 patients

Uncommon: affects more than 1 in 1,000, but less than 1 in 100 patients

Rare: affects more than 1 in 10,000, but less than 1 in 1,000 patients

The following side effects have been observed: Blood and lymphatic system disorders

Regular use of more than 1000 mg of ibuprofen per day may prolong bleeding time. This is particularly important for patients with bleeding disorders and patients taking anticoagulants (see also section "Use with other medicines").

Nervous system disorders

- Uncommon: headache, dizziness, insomnia, tinnitus, depression, Eye disorders
- Uncommon: blurred vision, Gastrointestinal disorders
- Common: stomach complaints, such as heartburn, stomach pain and nausea, diarrhea, vomiting, flatulence and constipation, and slight bleeding in the stomach and/or intestines that can in exceptional cases cause anemia
- Uncommon: perforation or gastrointestinal bleeding, black stools and vomiting blood, worsening of an existing bowel disease (ulcerative colitis or Crohn's disease), gastritis.

Liver and biliary disorders

- Very rare: yellow skin color, yellow deposits in the eyes
- Skin and subcutaneous tissue disorders
- Uncommon: skin rash, in the form of watery blisters, bumps or red to purplish spots, with or without itching. The severity of the skin rash can vary.

General disorders

Sometimes: if you experience fever, a general feeling of illness, and skin rash shortly after taking ibuprofen, you are allergic to ibuprofen. In these cases, you should stop taking ibuprofen and contact your doctor.

How do you store this medicine?

Store below 25°C. Keep the tablets in their original packaging to protect them from moisture.

Keep out of sight and reach of children.

The tablets are usable until the expiry date stated on the packaging and blister pack, which is labeled as "EXP".