

Package leaflet: information for the user

Ibuprofen 400 mg, tablets

Ibuprofen 600 mg, tablets

Information for the user

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Ibuprofen and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

## 1. WHAT IS IBUPROFEN AND WHAT IS IT USED FOR?

Ibuprofen belongs to the group of non-steroidal anti-inflammatory drugs (NSAIDs). It has anti-inflammatory, analgesic, and antipyretic properties.

Ibuprofen tablets are used for various types of pain such as toothache, headache, menstrual pain, muscle pain, and rheumatic pain. Also for fever and pain in flu and colds and after vaccination, for pain and inflammation in acute and chronic joint rheumatism; for painful inflammations of the musculoskeletal system and for pain after dental procedures and surgeries.

## 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

- When you suffer from severe heart failure (insufficient pumping power of the heart).
- if you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- in case of a previous occurrence of gastrointestinal bleeding or perforation due to NSAID use.
- if you have experienced allergic reactions or asthma attacks, shortness of breath, a blocked nose, or skin rash with itching and formation of welts after previous use of acetylsalicylic acid or other anti-inflammatory, pain-relieving, and fever-reducing medications.
- if you have previously had a bleeding or perforation of the gastrointestinal tract as a result of NSAID use.

- if you suffer from or have ever suffered from any of the following conditions: a stomach ulcer, a duodenal ulcer, gastrointestinal bleeding, or a brain hemorrhage.
- if you suffer from active or previously recurrent stomach ulcer/bleeding (two or more distinct episodes of proven ulceration or bleeding).
- if you suffer from severe liver failure or severe kidney failure (functioning of your kidneys and/or liver is greatly reduced).
- if you have a tendency to bleed or are being treated with anticoagulant medications.
- when you are in the third trimester of pregnancy.

When should you be extra careful with this medicine?

Signs of an allergic reaction to this medicine, including breathing difficulties, swelling of the face and neck region (angioedema), chest pain have been reported for ibuprofen. Stop using Ibuprofen immediately and contact your doctor or emergency services immediately if you experience any of these signs.

Severe 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 connection with ibuprofen treatment. Stop using ibuprofen and seek immediate medical help if you experience any of the symptoms related to these severe skin reactions as described in section 4.

Heart conditions

Anti-inflammatories/painkillers like ibuprofen may be associated with a small increased risk of heart attack or stroke, especially 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 medicine 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 the legs or feet due to narrowed or blocked arteries), or a stroke (including 'mini-stroke' or transient ischemic attack 'TIA').
- have high blood pressure, diabetes, or high cholesterol, have a family history of heart problems or stroke, or if you smoke.

Gastrointestinal disorders

The use of Ibuprofen with a certain group of pain-relieving medications that also have anti-inflammatory and antipyretic effects (NSAIDs) including selective COX-2 inhibitors should be avoided.

Gastrointestinal bleeding, ulcers, and perforation, which can be fatal, have been reported with the use of ibuprofen.

Skin reactions

Severe skin reactions have been reported with the use of this medication. Stop taking this medication and seek immediate medical help if you develop a rash, lesions on the mucous membranes, blisters, or other allergic reactions. These may be the first signs of a very serious skin

reaction. See section 4. The risk of these reactions is greatest during the first month of treatment.

In the case of chickenpox (varicella), it is advised not to use ibuprofen.

Contact your doctor or pharmacist before taking this medication if you:

- Are elderly, as you may be more likely to experience side effects, particularly bleeding and perforation of the gastrointestinal tract, which can be fatal.
- Have had a stomach or duodenal ulcer, and patients with bleeding disorders, liver or kidney dysfunction, high blood pressure, or heart conditions should be extra cautious when using ibuprofen.
- experience gastrointestinal bleeding, indicated by black, very foul-smelling stools, blood abnormalities (e.g., spontaneous bruising on the skin and mucous membranes or persistent sore throat), or significant liver dysfunction (e.g., yellowing of the skin or eyelids), the treatment with ibuprofen should be discontinued. In this case, contact your doctor.
- have an infection – see section “Infections” below.

Have impaired kidney function. Your doctor may prescribe you less ibuprofen than stated under the section “Dosage”.

After prolonged use, high doses, and careless use of painkillers, headaches may occur which cannot be treated with a larger amount of the medication at a time. If this situation occurs, you should report it to the doctor (see Side effects). The risk of side effects is minimized by using the lowest effective dose for the shortest possible time.

### Infections

Ibuprofen can mask symptoms of infections, such as fever and pain. Therefore, it is possible that Ibuprofen delays the 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 having an infection, and the symptoms of your infection persist or worsen, you should consult a doctor immediately.

Are you taking any other medications?

Note: the following comments may also apply to the use of medications some time ago or soon. The medications mentioned in this section may be known to you under a different name, often the brand name. In this section, only the name of the active substance or the group of active substances of the medication is mentioned and not the brand name! Therefore, always check the packaging or the leaflet to see what the active substance is of the medications you are using.

Ibuprofen can affect or be affected by other medications. For example:

- blood thinners (these are medications that prevent blood clotting, e.g., aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- blood pressure reducers (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists, such as losartan)

- Corticosteroids (adrenal cortex hormone with, among other things, anti-inflammatory effects, e.g., prednisolone), as they can increase the risk of stomach ulcers or stomach bleeding.
- Methotrexate (in the treatment of rheumatism), because the concentration of methotrexate can be increased 24 hours before or after taking Ibuprofen.
- Digoxin (heart medication).
- Phenytoin (for epilepsy).
- Lithium (for manic depression).

Some other medications can also affect, or be affected by, treatment with Ibuprofen. Therefore, always consult your doctor or pharmacist before using Ibuprofen in combination with other medications.

#### Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medication.

#### Fertility

This product belongs to a group of medications (NSAIDs) that can adversely affect female fertility when used. This is reversible by stopping the use of this medication.

#### Pregnancy

Do not use this medicine in the last three months of pregnancy; it can harm your unborn child or cause problems during delivery. Your unborn child may experience kidney and heart problems. The medicine can affect your and your baby's susceptibility to bleeding and cause the delivery to occur later or last longer than expected. Do not use this medicine during the first 6 months of pregnancy unless absolutely necessary and recommended by your doctor. If you need to be treated during this period or while trying to become pregnant, the lowest possible dose should be used, and the treatment should be kept as short as possible. From week 20 of pregnancy, this medicine - if used for more than a few days - can cause your unborn child to develop kidney problems, which may result in too little amniotic fluid around the child (oligohydramnios) or narrowing of a blood vessel in your baby's heart (ductus arteriosus). If you need to be treated for more than a few days, your doctor may recommend additional monitoring.

#### Breastfeeding

Ibuprofen passes into breast milk. Therefore, consult your doctor before deciding to breastfeed.

#### Driving and using machines

When using ibuprofen, you may experience dizziness. If you become dizzy, you should take this into account and it may be necessary not to participate in traffic or operate machines.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

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 (see section 2).

If the lowest effective dosage is used, for the shortest possible period needed to combat the symptoms, side effects can be minimized (see "Take special care with Ibuprofen").

Always follow the usage prescribed by your doctor. Below are some common dosages. The usage prescribed by your doctor may however, differ from this. Try to take the doses at the same times each day. Recommended dosages:

#### Rheumatism and other joint disorders

1200-1600 mg per day divided over 3-4 administrations. In severe cases, the dosage can be temporarily increased to a maximum of 2400 mg per day, divided over 4 administrations, until the acute phase is under control.

#### Pain after dental procedures and surgeries and menstrual pain

Initial dosage: 1200 mg per day divided over 3-4 administrations. If necessary, the dosage can be increased to 1600 mg per day divided over 3-4 administrations.

#### Fever and pain with flu and cold and after vaccination, toothache, headache, muscle pain, and rheumatic pain

Adults and children from 12 years: initial dosage 400 mg, if necessary followed by 200-400 mg every 4-6 hours. Maximum 1200 mg per day.

Take the tablets with a glass of water, during or shortly after a meal.

Rheumatic patients who suffer from morning stiffness can take the first administration immediately after waking up on an empty stomach to achieve a quick effect.

#### Have you used too much of this medicine?

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

The symptoms of overdose can include nausea, stomach pain, vomiting (possibly with blood), bleeding in the stomach and intestines (see also section 4 below), diarrhea, headache, ringing in the ears, confusion, and rapidly moving eyes. At high dosages, drowsiness, chest pain, palpitations, reduced consciousness, muscle spasms throughout the body (convulsions, especially in children), feeling weak and dizzy, blood in urine, a low amount of potassium in your blood, feeling cold

body sensation and breathing problems have been reported. Acute kidney failure may occur. Furthermore, there may be low blood pressure.

#### Have you forgotten to use this medicine?

If you have forgotten to take a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. If you have forgotten to take more than one dose, consult your doctor.

If you stop taking this medicine?

Always contact your doctor if you want to stop using this medicine, as the pain-relieving and anti-inflammatory effects will diminish after a few days and the original symptoms may return.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can cause side effects, although not everyone gets them. Medicines like Ibuprofen may be associated with a small increased risk of a heart attack ("myocardial infarction") or stroke.

Stop using ibuprofen and seek immediate medical attention if you experience any of the following symptoms:

- Reddish, non-raised, round spots (target lesions) on the trunk, often with central blisters, skin peeling, sores in the mouth, throat, nose, genitals, and eyes. These severe forms of skin rash may be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- Widespread rash, high body temperature, and enlarged lymph nodes (DRESS syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the start of treatment (acute generalized exanthematous pustulosis).

In the event that the product information already contains similar or stricter advice regarding SCARs, the similar or stricter advice remains valid and should be maintained.

In addition to the intended effect, a medicine sometimes also has unwanted effects, so-called side effects. The following side effects may occur with the use of Ibuprofen:

- indigestion with symptoms of fullness in the upper abdomen, pain in the stomach area, belching, nausea, vomiting, and heartburn (dyspepsia), flatulence, constipation, abdominal pain and diarrhea, gastrointestinal bleeding and risk of an ulcer, perforation, blood in the stool, itching, burning sensation and irritation of the rectal mucosa, swollen mucosa due to excessive blood supply, vomiting blood and worsening of inflammation of the digestive system (Crohn's disease).
- dizziness, headache, ringing in the ears, drowsiness, insomnia
- fluid retention (especially around the ankle)
- swollen eyes, blurred vision, and eye irritations
- skin rash and itching (due to hypersensitivity)
- severe form of skin reactions with blistering including Stevens-Johnson syndrome (a condition with red blisters, erosion, bloody or crust-covered skin) and toxic epidermal necrolysis (a disease with blistering and peeling of the top skin layer)
- changes in blood composition
- fluid retention (edema formation)
- high blood pressure (hypertension)
- heart failure

- a severe skin reaction known as DRESS syndrome may occur. Symptoms of DRESS include: skin rash, fever, swelling of the lymph nodes, and an increase in eosinophils (a type of white blood cell).
- A red rash on your skin with bumps under the skin and blisters. The bumps contain pus. The rash is mainly located in your skin folds, trunk, and upper limbs and is accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis AGEP). Stop taking this medicine if you experience these symptoms and seek medical help immediately. Frequency not known. See also section 2.
- skin may become sensitive to light – frequency not known
- chest pain, which may be a sign of a possible serious allergic reaction called Kounis syndrome

If you experience a sore throat or bruising on the skin or mucous membranes, you should consult your doctor.

In case of bleeding from the gastrointestinal tract or if the aforementioned side effects occur in severe form or unexpected side effects occur, you should contact your doctor or pharmacist.

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb ([www.lareb.nl](http://www.lareb.nl)). By reporting side effects, you can help us obtain more information about the safety of this medicine.

### 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store Ibuprofen tablets in the original packaging in a dry place at room temperature (15 - 25 °C).

Do not use this medicine after the expiry date. It can be found on the packaging after "Do not use after:" and on the blister packs after "Exp". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

### 6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is ibuprofen

The other substances in this medicine are: lactose, microcrystalline cellulose, maize starch, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, glyceryl triacetate, and the colorants titanium dioxide (E171) and erythrosine (E127).

What do Ibuprofen tablets look like and what is in a package?

The tablets are pink colored.

The tablets are packaged in boxes each containing 3 blister packs of 10 tablets.

Marketing authorization holder and manufacturer

Marketing authorization holder:

GenRx B.V. Dijkgraaf 30

6921 RL Duiven

Manufacturer:

FAL Duiven BV Dijkgraaf 30

6921 RL Duiven

Ibuprofen tablets are registered under RVG 18544 (400 mg tablets) and RVG 18545 (600 mg tablets).

This leaflet was last approved in February 2025.