Package leaflet: Information for the patient

Ibuprofen CF 200 mg, filmomhulde tabletten
Ibuprofen CF 400 mg, filmomhulde tabletten
Ibuprofen CF 600 mg, filmomhulde tabletten
Ibuprofen CF 800 mg, filmomhulde tabletten
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 <Product name> is and what it is used for

<Product name> contains the active substance ibuprofen and belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs). <Product name> reduces fever, relieves pain and has an anti-inflammatory effect.

<Product name> is used for symptomatic treatment of pain and inflammation in arthritic diseases (e.g. rheumatoid arthritis), degenerative arthritic conditions (e.g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries in adults and adolescents older than 12 years (≥ 40 kg).

<Product name> 200 mg is also indicated for symptomatic treatment of mild to moderate pain and fever in adults, adolescents and children 6–12 years (> 20 kg).

<Product name> 400 mg is also indicated for symptomatic treatment of mild to moderate pain and fever in adults and adolescents older than 12 years (≥ 40 kg).

<Product name> 600 mg is indicated in adults and adolescents from 50 kg body weight (15 years and above).

<Product name> 800 mg is indicated in adults.

2. What you need to know before you <take> <use> <Product name>

DO NOT take <Product name>
- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have a stomach ulcer or duodenal ulcer or have had recurrent ulcer or bleeding in the stomach or intestine

- if you have severe liver or kidney disease
- if you have severe heart failure
- if you have an increased tendency to bleed
- if you previously have had bleeding or perforation in your stomach or intestine when treated with <Product name> or a similar product (other NSAIDs)
- if you are in the last three months of pregnancy
- if you have experienced allergic reactions (e.g. breathing difficulties, nasal obstruction, rash) to acetylsalicylic acid or other anti-inflammatory drugs (NSAIDs)

Do not take <Product name> if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking <Product name> if you
- have asthma, runny nose (chronic rhinitis) or allergic diseases since <Product name> can cause difficulty breathing, hives or a serious allergic reaction when you have any of these conditions
- have certain disorders of the immune system (mixed connective tissue disorders and systemic lupus erythematosus (SLE), 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
- have impaired kidney or liver function
- 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
- have inflammatory bowel diseases, previous stomach ulcer or other increased tendency to bleed
- are dehydrated, as there is a risk of kidney impairment, especially in dehydrated adolescents and the elderly
- have an infection - please see heading "Infections" below

Do not take <Product name> if you are planning a pregnancy. Consult your doctor first. See also section "Pregnancy, breast-feeding and fertility".

This product belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine. See also section "Pregnancy, breast-feeding and fertility".

<u>Lowest effective dose</u>
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 taking several NSAID products at the same time should be avoided.

<u>Long-term use</u>
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.

<u>Heart attack and stroke</u>
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.

<u>Gastrointestinal bleeding, ulceration or perforation</u>

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 <Product name>.

Serious 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 generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using <Product name> and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Infections
<Product name> may hide signs of infections such as fever and pain. It is therefore possible that <Product name> 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.

During chicken pox it is advisable to avoid use of this medicine.

Other warnings
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 <Product name> immediately and contact your doctor or medical emergencies immediately if you notice any of these signs.

<Product name> belongs to a group of medicines which may impair fertility in women. This is reversible upon stopping the medicine. It is unlikely that using this medicine occasionally will affect your chances of becoming pregnant. However, talk to your doctor before taking ibuprofen if you have problems becoming pregnant (see section on “Pregnancy, breast-feeding and fertility” below).

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 kidney impairment in dehydrated children and adolescents. <Product name> should not be taken by children under 6 years of age. <Product name> 800 mg is not suitable for children under the age of 12 years.

Other medicines and <Product name>
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, have recently taken or might take any other medicines, including medicines obtained without a prescription.

<Product name> may affect or be affected by treatment with certain medicines, including those to treat/prevent:
- tumours and immune system disorders (methotrexate)
- manic depressive illness (lithium)
- irregular heartbeat (digoxin)
- pain (acetylsalicylic acid)

- thromboembolic disorders (medicines that are anti-coagulants, i.e. thin blood/prevent clotting, e.g., acetylsalicylic acid, dicumarol, warfarin, ticlopidine)
- depression (medicines called SSRIs - selective serotonin reuptake inhibitors)
- high blood pressure (medicines that reduce high blood pressure, e.g. 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)
- bacterial infections (some antibiotics including aminoglycosides)
- fungal infections (antifungals, particularly voriconazole or fluconazole)
- diabetes mellitus (sulphonylureas)
- high cholesterol (cholestyramine)
- human immunodeficiency virus (HIV) infection (zidovudine)

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

<Product name> with food, drink and alcohol
<Product name> can be used together with food and drinks. <Product name> can be given on an empty stomach for faster relief. If <Product name> is taken together with alcohol, side effects may be increased.

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.

Pregnancy
Do not take <Product name> 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 <Product name> 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, <Product name> 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 passes into breast milk but is not likely to have an effect on the breast-feeding child when used for short-term treatment. However, consult a doctor if using <Product name> more than occasionally while breast-feeding.

Fertility
The use of ibuprofen may affect fertility. The use of ibuprofen is not recommended while attempting to conceive or during fertility tests.

Driving and using machines
<Product name> may impair reactions in some people, for example due to side effects such as visual disturbances, dizziness or drowsiness. 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.

<Product name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take <Product name>

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

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).

Dosage

Always allow 4-6 hours between doses.

Adults and adolescents (12-18 years old, 40 kg and above)
Rheumatic conditions and painful swelling and inflammation after soft tissue injuries
The recommended dose is 400 mg-800 mg of ibuprofen 3 times daily. For faster relief of stiffness in the morning, the first dose can be given on an empty stomach. Maximum daily dose: 2 400 mg.

Pain of mild to moderate intensity
The recommended dose is 200 mg-400 mg of ibuprofen as a single dose or 3-4 times daily. Single doses exceeding 400 mg have not been shown to have any additional painkilling effect. Maximum daily dose: 1 200 mg.

Fever
The recommended dose is 200 mg-400 mg of ibuprofen 1-3 times daily, as required.
Maximum daily dose: 1 200 mg.

Use in children 6-12 years (over 20 kg)
Mild to moderate pain and fever: The recommended dose is 200 mg of ibuprofen 1-3 times daily.
Maximum daily dose: 20 mg/kg body weight, but not more than 600 mg.

<Product name> 800 mg is not suitable for children under the age of 12 years.

Elderly
If you are elderly, you should always consult your doctor before using <Product name>. You will be more prone to side effects, especially bleeding, ulcers and perforation in the gastrointestinal tract, which may be fatal. Your doctor will advise you accordingly.

Reduced liver or kidney function
If you have severe liver and kidney disease or are elderly your doctor will tell you the lowest possible dose.

Method of administration
<Product name> is for oral use.

Take the tablets with a glass of water. The tablets should be swallowed whole, without chewing, crushing or breaking to prevent discomfort in the mouth or throat irritation.

Patients with a sensitive stomach are advised to take the tablets together with food. If taken shortly after eating, the onset of action of ibuprofen may be delayed.

If you take more <Product name> than you should
If you have taken more <Product name> 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), 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, renal tubular acidosis (accumulation of acid in body), low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

Activated charcoal can be administered, especially within one hour of ingesting a potentially toxic amount.

If you forget to take <Product name>
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, this medicine can cause side effects, although not everybody gets them.

Stop taking <Product name> and contact a doctor immediately if you develop any of the following:
- Angioedema (an uncommon side effect) with symptoms such as:
  - swelling of the face, tongue or throat
  - difficulties swallowing
  - hives and difficulties breathing
- 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.
  <Product name> may cause a reduction in the number of white blood cells (agranulocytosis) with decreased resistance to infection (an uncommon side effect). It is important to inform your doctor about your medicine.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the 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).
- 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 generalised exanthematous pustulosis).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Other side effects
Common (may affect up to 1 in 10 people):
- Headache, light-headedness
- 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)
- Stuffy and runny nose (rhinitis)
- Hypersensitivity
- Difficulty sleeping (insomnia), anxiety
- Visual disturbances, hearing impairment
- Bronchial spasm, asthma
- Mouth ulceration
- Stomach ulcer, intestinal ulcer, ruptured stomach ulcer, inflammation of mucous membrane of stomach
- Hepatitis, jaundice, abnormal liver function
- Itching, small bruises in skin and mucous membranes
- Photosensitivity
- Impaired kidney function
- Changes in blood count
- Anaemia (a reduction in red blood cells or haemoglobin, which can make the skin pale and may lead to weakness)
- Drowsiness
- Tingling sensation

Rare (may affect up to 1 in 1 000 people):
- Non-bacterial meningitis
- Allergic reaction
- Depression, confusion
- Impaired vision, tinnitus (ringing in ears), dizziness
- Liver damage and fluid retention in body

Very rare (may affect up to 1 in 10 000 people):
- Inflammation of the pancreas, liver failure

Not known (frequency cannot be estimated from the available data):
- Worsening of ulcers in the large intestine (colitis) and Crohn's Disease (bowel disease)
- Heart failure, heart attack, high blood pressure. <Product name> can prolong bleeding time.
- Skin becomes sensitive to light (photosensitivity reactions)

Exceptionally, serious infections of the skin during chicken pox may occur. When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterised by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of ibuprofen it is recommended to see your doctor immediately.

Medicines like <Product name> 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or the blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 <Product name> contains

The active substance is ibuprofen. Each film-coated tablet contains 200 mg, 400 mg, 600 mg or 800 mg of ibuprofen.

The other ingredients are:
Tablet core: cellulose, microcrystalline (E460), starch, pregelatinised (maize), povidone, sodium laurilsulfate (E487), croscarmellose sodium (E468), silica, colloidal anhydrous (E551), magnesium stearate (E572).

Film coating: titanium dioxide (E171), hypromellose (E463), hydroxypropylcellulose (E464), macrogol.

What <Product name> looks like and contents of the pack

<Product name> 200 mg: Round (9 mm in diameter) white to off white film coated tablet debossed with 'G2' on one side.

<Product name> 400 mg: Oval (14 mm x 8 mm in diameter) white to off white film coated tablet debossed with 'I 6' on one side.

<Product name> 600 mg: Caplet (17 mm x 9 mm) white to off white film-coated tablet debossed with ‘I 7’ on one side.

<Product name> 800 mg: Caplet (19 mm x 9 mm) white to off white film-coated tablets debossed with ‘I 10’ on one side.

Pack sizes:

200 mg: PVC/Alu blisters containing 50, 100.
PVC/Alu perforated unit dose blisters containing 50x1, 100x1 tablets.
400 mg: PVC/Alu blisters containing 20, 30, 50, 100.
PVC/Alu perforated unit dose blisters 20x1, 30x1, 50x1, 100x1 tablets
600 mg: PVC/Alu blisters containing 10, 20, 30, 40, 50, 60, 70, 80, 90, 100.
PVC/Alu perforated unit dose blisters 10x1, 20x1, 30x1, 40x1, 50x1, 60x1, 70x1, 80x1, 90x1, 100x1 tablets
800 mg: PVC/Alu blisters containing 20, 30, 50, 60.
PVC/Alu perforated unit dose blisters 20x1, 30x1, 50x1, 60x1.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Fabrikant:
Pharmazet Group s.r.o.
Třtinová 260/1,
196 00 Praag
Tsjechië

STADA Arzneimittel AG
Stadastrasse 2 - 18
61118 Bad Vilbel
Duitsland

Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Clonmel Healthcare Ltd
Waterford Road
E91 D768 Clonmel, Co. Tipperary
Ierland

STADA M&D SRL
Str. Trascăului, nr 10,
401135, Turda
Roemenië

In het register ingeschreven onder

Ibuprofen CF 200 mg, filmomhulde tabletten	RVG 133285
Ibuprofen CF 400 mg, filmomhulde tabletten	RVG 133286
Ibuprofen CF 600 mg, filmomhulde tabletten	RVG 133287
Ibuprofen CF 800 mg, filmomhulde tabletten	RVG 133288

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

België	Ibuprofen EG 600 mg filmomhulde tabletten
	Ibuprofen EG 800 mg filmomhulde tabletten
Duitsland	Ibuprofen STADA 400 mg Filmtabletten
	Ibuprofen STADA 600 mg Filmtabletten
	Ibuprofen STADA 800 mg Filmtabletten
Estland	Ibuprofen STADA Arzneimittel
Ierland	Ibuprofen Rx Clonmel 200 mg film-coated tablets
	Ibuprofen Rx Clonmel 400 mg film-coated tablets
Letland	Ibuprofen STADA Arzneimittel 600 mg apvalkotās tabletes
Litouwen	Ibuprofen STADA Arzneimittel 600 mg plėvele dengtos tabletės
Luxemburg	Ibuprofen EG 600 mg comprimés pelliculés
	Ibuprofen EG 800 mg comprimés pelliculés
Nederland	Ibuprofen CF 200 mg, filmomhulde tabletten
	Ibuprofen CF 400 mg, filmomhulde tabletten

	Ibuprofen CF 600 mg, filmomhulde tabletten Ibuprofen CF 800 mg, filmomhulde tabletten
Spanje	Ibuprofeno STADAFARMA 400 mg comprimidos recubiertos con película EFG
Slowakije	Ibuprofen STADA Arzneimittel 400 mg filmom obalené tablety

Deze bijsluiter is voor het laatst goedgekeurd in december 2025.