Package leaflet: Information for the patient

Ibuprofen STADA 200 mg, filmomhulde tabletten
Ibuprofen STADA 400 mg, filmomhulde tabletten
ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve
  - after 3 days in adolescents.
  - after 3 days if you have fever and 4 days for the treatment of pain in adults.

What is in this leaflet

1. What <Product name> is and what it is used for

<Product name> contains the active substance ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) which work by reducing pain and fever.

<Product name> is used for the short-term symptomatic treatment of mild to moderate pain such as headache, period pain and toothache, and/or for the short-term symptomatic treatment of fever associated with the common cold.

<Product name> is indicated in adults and adolescents with body weight from 40 kg (12 years of age and above).

2. What you need to know before you take <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).
- have ever suffered from an allergic reaction such as bronchospasm, asthma, runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat (angioedema) after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs)
- have ever had bleeding or perforation in your stomach or intestine related to previous NSAID therapy
- currently have an ulcer or bleeding in your stomach or small intestine (duodenum), or if you have had two or more of these episodes of ulcers or bleeding in your stomach or duodenum (peptic ulcers) in the past
- suffer from severe heart failure
- suffer from severe liver failure or severe kidney failure

- are in the last three months of pregnancy

Warnings and precautions
Talk to your doctor or pharmacist before taking <Product name> if you:
- have systemic lupus erythematosus (SLE, an autoimmune disease) or mixed connective tissue disease (an autoimmune disease affecting connective tissue)
- have chicken pox (varicella), as it is advisable to avoid use of this medicine if you suffer from this disease
- have or have ever had gastrointestinal disorders (ulcerative colitis, Crohn's disease), as your condition may get worse
- have certain hereditary blood formation disorders (e.g. acute intermittent porphyria)
- suffer from reduced liver or kidney function
- have just had major surgery
- are hypersensitive (allergic) to other substances
- suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders, because you are at higher risk of allergic reactions. The allergic reactions may present as asthma attacks (so-called analgesic asthma), sudden swellings (Quincke's oedema) or a nettle rash
- are dehydrated
- have heart problems including heart failure, angina pectoris (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), 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 an infection - please see heading "Infections" below
- if you 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

The risk of side effects increases with an increasing dose of the product and in the elderly. It is therefore necessary to start treatment with the lowest possible dose and continue treatment for the shortest possible time necessary to treat symptoms.

<u>Infections</u>
<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.

<u>Effects on the cardiovascular system</u>
Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

<u>Effects on the gastrointestinal tract</u>
Combined use of <Product name> with other non-steroidal anti-inflammatory drugs (NSAIDs), including so-called COX-2 inhibitors (cyclooxygenase-2 inhibitors), should be avoided.

Bleeding of the gastrointestinal tract, ulcers and perforation
Bleeding of the gastrointestinal tract, ulcers and perforation, sometimes with fatal outcome, have been reported with all NSAIDs. These have occurred at any time during therapy, with or without previous warning symptoms or a history of serious gastrointestinal events.

The risk of experiencing gastrointestinal bleeding, ulcers and perforation is higher with increasing NSAID dose and is higher in patients with a history of ulcers, especially with complications of bleeding or perforation (see section 2 “DO NOT take <Product name>") and in elderly patients. These patients should start treatment at the lowest available dose. For these patients, as well as patients requiring additional treatment with low-dose acetylsalicylic acid or other medicines that may increase the risk of gastrointestinal disorders, combination treatment with protective medicines (e.g. misoprostol or proton pump inhibitors) should be considered.

If you have a history of side effects affecting the gastrointestinal tract - especially if you are elderly - you should contact a doctor in the event of unusual abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of therapy.

Caution is advised if you are also taking other medicines that may increase the risk of ulcers or bleeding, e.g. oral corticosteroids, anticoagulants (blood-thinners) such as warfarin, selective serotonin reuptake inhibitors (used to treat psychiatric disorders including depression) or platelet aggregation inhibitors such as acetylsalicylic acid (see section 2 “Other medicines and <Product name>).

Treatment must be stopped and a doctor consulted if you develop gastrointestinal bleeding or ulcers during the 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.

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.

Blood clotting disorders
Ibuprofen can temporarily inhibit blood platelet function (blood platelet aggregation). Patients with blood clotting disorders should therefore be carefully monitored.

Long-term use
Prolonged use of any type of analgesics for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of medication overuse headache (MOH) should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

During prolonged use of ibuprofen regular monitoring of liver and kidney function and blood counts is required.

In general, habitual intake of painkillers, especially when several pain-killing medicines are combined, may lead to permanent kidney damage. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

Fertility in women
<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).

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

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
<Product name> may affect or be affected by some other medicines. For example:
- anti-coagulants and anti-platelet agents (i.e. to thin blood/prevent clotting e.g. acetylsalicylic acid, warfarin, ticlopidine)
- 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 diuretics (used to increase urine output)
- other non-steroidal anti-inflammatory drugs (NSAIDs) including cyclooxygenase-2 inhibitors or acetylsalicylic acid - increased risk of gastrointestinal ulcers or bleeding
- digoxin (used to treat various heart conditions) since the effect of digoxin may be enhanced
- lithium (used to treat depression and mania) since the effect of lithium may be enhanced
- phenytoin (used to treat seizures/epilepsy) since the effect of phenytoin may be enhanced
- zidovudine (used to treat HIV/AIDS)
- glucocorticoids (used in the treatment of inflammatory conditions) since this may increase the risk of gastrointestinal ulcers or bleeding
- methotrexate (used to treat certain cancers and autoimmune diseases)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus since kidney damage may occur
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin since the risk of convulsions (fits) may be increased
- aminoglycosides (a type of antibiotic) since NSAIDs may decrease excretion of aminoglycosides
- mifepristone since NSAIDs can reduce the effect of mifepristone
- diuretics (water tablets) since the effect of the diuretics may be weakened
- potassium-sparing diuretics since this may lead to hyperkalaemia
- probenecid or sulfinpyrazone (for treating gout) since the excretion of ibuprofen may be delayed
- cholestyramine (used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes) since the blood sugar levels can be affected
- voriconazole or fluconazole (type of anti-fungal medicines) (CYP2C9 inhibitors), since the effect of ibuprofen may increase. Reduction of the ibuprofen dose should be considered, particularly when high-dose ibuprofen is used with either voriconazole or fluconazole
- Ginkgo biloba (herbal medicine) - increased risk of bleeding.
- ritonavir (antiviral agent) may increase the plasma concentrations of NSAIDs
- alcohol, bisphosphonates (used in osteoporosis) or pentoxifylline (used in peripheral arterial circulatory problems) may increase the likelihood of gastrointestinal side effects and the risk of bleeding and ulcers
- baclofen (a muscle relaxant) because of elevated baclofen toxicity

Some other medicines may also affect or be affected by the treatment with <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

Avoid drinking alcohol since it may enhance the side effects of this medicine, especially those affecting the stomach, intestines or brain.

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 for advice before taking this medicine.

Pregnancy
- 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 to 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.

Breast-feeding
Only small amounts of ibuprofen pass into human milk and breast-feeding will usually not need to be stopped during short-term use of ibuprofen at the recommended dose for fever and pain.

Fertility
<Product name> 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.
The product belongs to a group of medicines (NSAIDs) which may impair fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines
Ibuprofen generally has no or negligible influence on the ability to drive and use machines. However, since at higher doses undesirable effects such as tiredness and dizziness may occur, the ability to react and the ability to take part actively in road traffic and to operate machines may be impaired in individual cases. This 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 described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

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).

The recommended dose is

Body weight (age)	Single dose	Maximum daily dose
≥ 40 kg (adults and adolescents aged 12 years and older)	200-400 mg	1 200 mg

The interval between doses should be of at least 6 hours.

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 reduced kidney or liver function, always consult a doctor before using <Product name>. Do not take this medicine if you suffer from severe liver or kidney failure.

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 effect of ibuprofen may be delayed.

Duration of treatment
If this medicine is required by adults for more than 3 days of fever, or for more than 4 days of pain, or if symptoms worsen, consult a doctor.

If this medicine is required by adolescents for more than 3 days or if the symptoms worsen, consult a doctor.

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 take 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. You can minimise the risk of side effects by taking the lowest effective dose for the shortest duration necessary to control your symptoms.

The list of the following side effects comprises all side effects that have become known under treatment with ibuprofen, also those under high-dose long-term therapy in rheumatism patients. The stated frequencies, which extend beyond very rare reports, refer to the short-term use of daily doses up to a maximum of 1 200 mg ibuprofen for oral dosage forms and a maximum of 1 800 mg for suppositories.

STOP TAKING <Product name> and contact a doctor immediately if you experience any of these symptoms:

- Symptoms of aseptic meningitis with headache, nausea, vomiting, high temperature, stiffness of the neck or clouding of consciousness (very rare: may affect up to 1 in 10 000 people). Patients with autoimmune disorders (SLE, mixed connective tissue disease) appear to be predisposed.
- Signs of gastrointestinal bleeding such as relatively severe epigastric (below the ribs) pain, passing blood in your faeces (stools/motions) or passing black tarry stools or vomiting any blood or dark particles that look like coffee grounds (uncommon: may affect up to 1 in 100 people).
- Signs of a severe allergic reaction, such as swelling of the face, tongue or throat, shortness of breath, increased heart rate, reduced blood pressure up to in life-threatening shock (very rare: may affect up to 1 in 10 000 people).
- Reddish, flat, target-like or circular patches on the abdomen, 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].
- 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 initiation of treatment (acute generalised exanthematous pustulosis).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- Loss of vision, blurred or disturbed vision (visual impairment) (uncommon: may affect up to 1 in 100 people).
- Problems in the blood cell production (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis) - first signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, nose and skin bleeding (very rare: may affect up to 1 in 10 000 people). In these cases, do not use any treatment with painkillers or medicinal products that reduce fever (antipyretic medicinal products).
- Swelling (oedema) and cloudy urine (nephrotic syndrome); inflammatory kidney disease (interstitial nephritis) that may lead to acute kidney failure. Reduced urine output, fluid accumulation within the body (oedema) and generally feeling unwell can be signs of kidney disease or even kidney failure (very rare: may affect up to 1 in 10 000 people).

Other side effects

Common (may affect up to 1 in 10 people)

- gastrointestinal symptoms such as acid reflux, stomach pain, nausea, diarrhoea, vomiting, wind (flatulence) and constipation
- minor gastrointestinal bleeding which may cause anaemia in exceptional cases

Uncommon (may affect up to 1 in 100 people)

- allergic (hypersensitivity) reactions with skin rash and itching, as well as asthma attacks (possibly with drop in blood pressure)
- headache
- feeling dizzy or tired

- agitation and irritability
- feeling drowsy
- difficulty sleeping
- sensation of spinning (vertigo)
- various skin rashes
- stomach or gut ulcer, potentially with bleeding and perforation (hole in the wall of the digestive tract)
- worsening of colitis (inflammation of the colon) and Crohn's Disease
- inflammation of stomach lining (gastritis)
- inflammation of the mucous membranes of the mouth with ulcers (ulcerative stomatitis)

Rare (may affect up to 1 in a 1 000 people)
- visual impairment that occurs, when a toxin damages the optic nerve (toxic optic neuropathy)
- loss of hearing
- ringing in ears (tinnitus)
- kidney tissue damage (papillary necrosis), elevated uric acid blood concentrations, elevated urea concentration in the blood

Very rare (may affect up to 1 in 10 000 people)
- inflammation of the pancreas (pancreatitis)
- inflammation of oesophagus (oesophagitis)
- diaphragm disease (formation of intestinal diaphragm-like strictures)
- impaired liver function, liver failure, acute hepatitis (inflammation of the liver), liver damage, particularly in case of prolonged treatment
- depression, psychotic reactions
- palpitations (feelings of having a fast-beating, fluttering or pounding heart), heart failure, myocardial infarction
- high blood pressure, vasculitis (inflammation of blood vessels)
- asthma, bronchospasm, dyspnoea (difficulty breathing)
- hair loss (alopecia)

Not known (frequency cannot be estimated from the available data)
- sensations like numbness, tingling, pins and needles
- impaired vision (optic neuritis)
- stuffy and runny nose (rhinitis)
- skin becomes sensitive to light (photosensitivity reactions)

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. Content of the pack and other information

What <Product name> contains

The active substance is ibuprofen. Each film-coated tablet contains 200 mg or 400 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 (E 171), 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.

Clear, transparent PVC/Aluminium blister pack in an outer carton box containing 10 or 12 tablets per blister or unit dose blister.

Pack sizes:

200 mg: PVC/Alu blisters containing 10, 12, 20, 24, 30, 40, 48, 50, 100.
PVC/Alu perforated unit dose blisters containing 10x1, 12x1, 20x1, 24x1, 30x1, 40x1, 48x1, 50x1, 100x1 tablets.

400 mg: PVC/Alu blisters containing 10, 12, 20, 24, 30, 40, 50, 100.
PVC/Alu perforated unit dose blisters containing 10x1, 12x1, 20x1, 24x1, 30x1, 40x1, 50x1, 100x1 tablets.

Not all pack sizes may be marketed.

Vergunninghouder:
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61118 Bad Vilbel
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Fabrikant:
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Roemenië

In het register ingeschreven onder

Ibuprofen STADA 200 mg, filmomhulde tabletten	RVG 133275
Ibuprofen STADA 400 mg, filmomhulde tabletten	RVG 133277

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

België	Ibuprofen EG 200 mg filmomhulde tabletten
	Ibuprofen EG 400 mg filmomhulde tabletten
Estland	Ibuprofen STADA Arzneimittel AG
Ierland	Ibuprofen Clonmel 200 mg film-coated tablets
	Ibuprofen Clonmel Max Strength 400 mg film-coated tablets
Letland	Ibuprofen STADA Arzneimittel AG 200 mg apvalkotās tabletes
	Ibuprofen STADA Arzneimittel AG 400 mg apvalkotās tabletes
Litouwen	Ibuprofen STADA Arzneimittel AG 200 mg plėvele dengtos tabletės
	Ibuprofen STADA Arzneimittel AG 400 mg plėvele dengtos tabletės
Luxemburg	Ibuprofen EG 200 mg comprimés pelliculés
	Ibuprofen EG 400 mg comprimés pelliculés
Malta	Easofen 200 mg film-coated tablets
	Easofen Max Strength 400 mg film-coated tablets
Nederland	Ibuprofen STADA 200 mg, filmomhulde tabletten
	Ibuprofen STADA 400 mg, filmomhulde tabletten
Slowakije	Ibuprofen STADA 400 mg filmom obalené tablety

Deze bijsluiter is voor het laatst goedgekeurd in december 2025.