

Package leaflet: Information for the patient
Ibuprofen Brill 200 mg Film-coated Tablets
Ibuprofen

The PL includes alternative texts for different legal status in different countries as follows:

- **Boxed texts** are only applicable for OTC versions.
- **[Grey shaded text in brackets]** are only applicable for prescription versions.

[For medicines available only on prescription:]

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. It includes any possible side effects not listed in this leaflet. See section 4].

[For medicines available without a prescription:]

<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. This includes any possible side effects not listed in this leaflet. See section 4..
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days with a fever and 5 days with pain.

What is in this leaflet:

1. What Ibuprofen Brill is and what they are used for
2. What you need to know before you take Ibuprofen Brill
3. How to take Ibuprofen Brill
4. Possible side effects
5. How to store Ibuprofen Brill
6. Contents of the pack and other information

1. What Ibuprofen Brill are and what are they used for

Ibuprofen Brill belongs to a group of medicines called NSAID (non-steroidal anti-inflammatory drugs) which work by reducing pain and fever.

Ibuprofen Brill is used for short term symptomatic treatment of mild to moderate pain such as headache (including migraine), dysmenorrhoea (period pain), dental pain, and fever and pain in common cold.

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

Do not take Ibuprofen Brill:

- if you are allergic to ibuprofen or any of the other ingredients of this medicine listed in section 6.
- if you have had allergic reactions such as asthma, runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat after you have taken medicines containing acetylsalicylic acid (such as aspirin) or other drugs for pain and inflammation (NSAIDs).
- if you have suffered from an ulcer or bleeding in the stomach or small intestine (duodenum related to previous use of drugs for pain and inflammation (NSAIDs)
- if you are suffering from an ulcer or bleeding in the stomach or small intestine (duodenum) or if you have had two or more of these episodes in the past
- if you suffer from severe liver, kidney or heart failure
- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- if you have any active bleeding (including in the brain)
- if you are in the last 3 months of pregnancy.
- if you suffer from a condition of unknown origin resulting in abnormal formation of blood cells
- if the patient is a child below 6 years of age (below 20 kg body weight)

Warnings and Precautions:

Talk to your doctor or pharmacist before taking Ibuprofen Brill.

- if you have Systemic Lupus erythematosus (SLE) or other autoimmune diseases
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria)
- if you have chronic inflammatory intestinal diseases such as inflammation of the colon with ulcers (ulcerative colitis), inflammation affecting the digestive tract (Crohn's disease), or other stomach or intestinal diseases
- if you have disturbances in the formation of blood cells
- if you have problems with normal blood clotting mechanism
- if you suffer from allergies, hay fever, asthma, chronic swelling of nasal mucosa, sinuses, adenoids, or chronic obstructive affections of the respiratory tract because the risk for developing narrowing of the airways with difficulty in breathing (bronchospasm) is greater
- if you suffer from circulation problems in the arteries of your arms or legs
- if you have liver, kidney, heart problems or high blood pressure
- if you have just had major surgery
- if you are in the first six months of pregnancy
- if you are breast-feeding
- if you are trying to get pregnant
- You have an infection - please see heading "Infections" below.

Older people If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal.

Ulcers, perforation and bleeding in the stomach or intestines

If you have earlier had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding, you should look out for any unusual symptoms in the abdomen, and report them at once to your doctor, especially if these symptoms occur at the beginning of treatment. This is because the risk for bleeding or

ulceration of the digestive tract is higher in this case, especially in elderly patients. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.

Bleeding, ulceration or perforation in the stomach or intestines may occur without any warning signs even in patients who have never had such problems before. It may also be fatal.

The risk of ulcers, perforation or bleeding in the stomach or intestines generally increases with higher doses of ibuprofen. The risk also increases if certain other medicines are taken at the same time as ibuprofen (see Other medicines and Ibuprofen Bril, below).

Skin reactions

Serious skin reactions have been reported in association with Ibuprofen Bril treatment. You should stop taking ibuprofen and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reactions (see section 4)..

Effects on the heart and brain

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 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.

Effects on the kidneys

Ibuprofen may cause problems with kidney function even in patients who have not had kidney problems before. This may result in swelling of the legs and may even lead to heart failure or high blood pressure in predisposed individuals.

Ibuprofen may cause kidney damage especially in patients who already have kidney, heart or liver problems, or are taking diuretics or ACE inhibitors, as well as in the elderly. Stopping ibuprofen however generally leads to recovery.

Infections

Ibuprofen Bril may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Bril 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.

Other precautions

In general the habitual use of (several sorts of) analgesics can lead to lasting severe kidney problems. This risk may be increased under physical strain associated with loss of salt and dehydration. Therefore it should be avoided.

Prolonged use of any type of painkiller for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued.

Ibuprofen may temporarily prolong bleeding time.

Ibuprofen may decrease your chance of becoming pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Consult a doctor before using Ibuprofen Brill if any above mentioned conditions concerns you.

Children and adolescents

Do not give this medicine to children under the age of 6 years (below 20kg body weight). There is a risk of renal impairment in dehydrated children and adolescents.

Other medicines and Ibuprofen Brill

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

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

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- methotrexate used to treat cancer and auto-immune diseases

- other NSAIDs
- methotrexate (used to treat cancer and auto-immune diseases)
- digoxin (for treatment of various heart conditions)
- phenytoin (used in prevention of the occurrence of epileptic seizures)
- lithium (used to treat depression and mania)
- diuretics (water tablets), including potassium-sparing diuretics
- medicines that reduce high blood pressure such as:
 - ACE-inhibitors such as captopril
 - beta-blockers such as atenolol medicines
 - angiotensin II receptor antagonists such as losartan
- cholestyramine (used in the treatment of high cholesterol)
- aminoglycosides (medicines against certain types of bacteria)
- SSRIs (medicines against depression) such as paroxetine, sertraline, citalopram
- moclobemide (a medicine to treat depressive illness or social phobia)
- ciclosporine, tacrolimus (for immuno-suppression after organ transplant)
- zidovudine or zalcitabine (used to treat patients with HIV)
- mifepristone
- probenecid or sulfinpyrazone (for treating gout)

- quinolone antibiotics
- sulphonylureas (to treat type 2 diabetes)
- corticosteroids (used against inflammations)
- bisphosphonates (used in osteoporosis, Paget's disease and to reduce high blood calcium levels)
- oxpentifylline ((pentoxifylline) used in the treatment of circulatory disease of the arteries of the legs or arms)
- baclofen (a muscle relaxant)
- fluconazole and variconazole – medicines to treat fungal infection

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

Ibuprofen Bril with food, drink and alcohol

Ibuprofen Bril is recommended to take with food, to avoid gastrointestinal problems.

Avoid alcohol since it may enhance the side effects of Ibuprofen, 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 or pharmacist for advice before taking this medicine.

Pregnancy

Ibuprofen must not be taken in the last 3 months of pregnancy since it may cause major heart, lung and kidney disorders in the unborn child.

If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions thus delaying the onset of delivery.

You should only use ibuprofen in the first 6 months of pregnancy after consulting your doctor and only when clearly necessary.

Breast-feeding

Ibuprofen appears in breast milk in a very small amount and breastfeeding will usually not need to be stopped during short-term treatments. If, however, longer treatment is prescribed, early weaning should be considered.

Fertility

This medicine belongs to a group of NSAIDs which may impair the fertility in women. This effect is reversible on stopping the medicine. It is not recommended to take ibuprofen if you are planning to become pregnant or if you have problem to become pregnant.

Driving and using machines

Ibuprofen generally has no adverse effects on the ability to drive or operate machinery. However since at high dosage side effects such as fatigue, somnolence, vertigo and visual disturbances may be experienced the ability to drive a car or operate machinery may be

impaired in individual cases. This effect is potentiated by simultaneous consumption of alcohol.

Ibuprofen Brill contains lactose

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

3. How to take Ibuprofen Brill

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.

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

The tablet should be swallowed whole with a glass of water. It is recommended that patients with sensitive stomach take Ibuprofen Brill with food.

Do not exceed the recommended dose or duration of treatment (5 days in a row)

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

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 ibuprofen dose depends on the patient's age and body weight.

The recommended dose is:

Mild to moderate pain and fever

Adults and adolescents older than 12 years weighing 40 kg or more):

1 or 2 tablets given as a single dose or 3 times a day with an interval of 4 to 6 hours.

The maximum daily dose should not exceed 6 tablets (1200 mg).

Children 6-9 years (20-29 kg):

1 tablet (200 mg) 1-3 times a day with intervals of 4 to 6 hours as required. The maximum daily dose should not exceed 600 mg.

Children 10-12 years (30-40 kg):

1 tablet (200 mg) 1-4 times a day with intervals of 4 to 6 hours as required. The maximum daily dose should not exceed 800 mg.

If in children aged from 6 years and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Period Pain

Adults and adolescents over 12 years of age (weighing 40 kg or more):

1 to 2 tablet to be taken 1-3 times a day, with an interval of 4-6 hours. The maximum daily dose should not be more than 6 tablets (1200mg)

Migraine headache

Adults and adolescents older than 12 years (weighing 40 kg or more):

2 tablets given as a single dose, with an interval of 4 to 6 hours. The maximum daily dose should not exceed 6 tablets (1200 mg). Single doses exceeding 400 mg have not been shown to have any additional analgesic effect.

If your condition has not improved or has worsened within 3 days with a fever and 5 days with pain, you should contact a doctor.

Older people: If you are elderly you should always consult your doctor before using Ibuprofen Brill since you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal. Your doctor will advise you accordingly.

Reduced kidney or liver function

If you suffer from reduced kidney or liver function, always consult your doctor before using Ibuprofen Brill. Your doctor will advise you accordingly.

If you take more Ibuprofen Brill than you should

If you have taken more Ibuprofen Brill 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 may be: nausea, vomiting (may be blood streaked) and stomach pain or diarrhoea. A buzzing in the ears, headache, vertigo and bleeding from the stomach or intestines may also occur. In more serious cases of overdose, drowsiness, chest pain, palpitations, loss of consciousness, excitation, disorientation, coma, convulsions (mainly in children), weakness, dizziness, blood in urine, cold body feeling, cramps (especially in children), blurred vision and eye problems, kidney failure, liver damage, low blood pressure, reduced respiration, bluish discolouration of lips, tongue and fingers, and increased bleeding tendency may all occur. Worsening of asthma in asthmatics can also occur.

If you forget to take Ibuprofen Brill

If you forget to take a dose, take it as soon as you can, except if there is less than four hours remaining until the time for the next dose.

Do not take 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, ibuprofen Brill can cause side effects, although not everybody gets them.

Undesirable effects are more likely with higher doses and longer duration of treatment.

Medicines such as Ibuprofen Brill may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Water retention (oedema), high blood pressure and heart failure have been reported in association with NSAIDs.

The following side effects are important and will require immediate action if you experience them. You should stop taking Ibuprofen Bril and see your doctor immediately if the following symptoms occur:

Common: may affect up to 1 in 10 people

- black tarry stools or blood-stained vomit (digestive tract ulcer with bleeding)

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

- swelling of the face, tongue or throat (larynx) which can cause great difficulty in breathing (angioedema), rapid heartbeat, severe fall in blood pressure or life threatening shock
- a sudden allergic reaction with shortness of breath, wheezing and drop of blood pressure
- severe rash with blisters on the skin especially on the legs, arms, hands and feet which can also involve the face and lips (erythema multiforme, Stevens-Johnson's syndrome). This can get even more severe, the blisters get larger and spread out and parts of the skin may slough off (Lyell's syndrome). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle

Not known: Frequency cannot be estimated from the available data

- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells)
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.

You should stop taking the medicine and contact your doctor as soon as possible if you develop the following side effects:

Very common: may affect more than 1 in 10 people

- heartburn, abdominal pain, indigestion

Uncommon: may affect up to 1 in 100 people

- blurred vision or other eye problems such as sensitivity to light
- hypersensitivity reactions such as skin rash, itching, asthma attacks (sometimes with low blood pressure)

Rare: may affect up to 1 in 1,000 people

- vision loss

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

- sudden filling of lungs with water resulting in difficulty to breathe, high blood pressure, water retention and weight gain

Other possible side effects with Ibuprofen Bril are:

Very common: may affect more than 1 in 10 people

- disturbances in the digestive tract, such as diarrhoea, feeling sick, vomiting, wind, constipation

Common: may affect up to 1 in 10 people

- digestive tract ulcer with or without perforation
- bowel inflammation and worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease) and complications of diverticula of the large bowel (perforation or fistula)
- microscopic bleeding from the intestine which may result in anaemia
- mouth ulcers and inflammation
- headache, sleepiness, vertigo, dizziness, fatigue, agitation, insomnia and irritability

Uncommon: may affect up to 1 in 100 people

- inflammation of the stomach lining
- kidney problems including development of oedema, inflammation of the kidneys and kidney failure
- runny nose
- difficulty breathing (bronchospasm)

Rare: may affect up to 1 in 1,000 people

- depression, confusion, hallucinations
- lupus erythematosus syndrome
- increase of blood urea nitrogen and other liver enzymes, decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation and prolonged bleeding time, decrease of serum calcium and increase in serum uric acid values

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

- unpleasant awareness of heart beat, heart failure, heart attack or high blood pressure
- disorders of blood cell formation (with symptoms like: fever, sore throat, surface mouth ulcers, flu-like symptoms, severe fatigue, nasal and skin bleeding)
- ringing or buzzing in the ears
- inflammation of the oesophagus or pancreas
- narrowing of the bowel
- acute inflammation of the liver, yellowish discolouration of the skin or whites of the eyes, liver dysfunction, damage or failure
- inflammation of the brain membrane (without bacterial infection)
- damage of the kidney tissue
- hair loss

Not known: frequency cannot be estimated from the available data

- drug induced skin eruptions
- skin becomes sensitive to light

Ibuprofen Brill 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.

During treatment with ibuprofen, some cases of meningitis (presenting as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed in patients with

existing autoimmune disorders such as systemic lupus erythematosus or mixed connective tissue disease.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes many possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

[to be completed nationally]

5. How to store Ibuprofen Brill film-coated tablets

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

Do not use Ibuprofen Brill after the expiry date which is stated on the blister, carton or bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ibuprofen Brill contains

The active substance is ibuprofen.

Each film-coated tablet contains 200mg of ibuprofen.

The other ingredients in the core tablet are; microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, polyvinyl povidone, maize starch, sodium lauril sulfate and magnesium stearate

The tablet coating contains hydroxypropyl cellulose, hypromellose, macrogol 400 and titanium dioxide.

What Ibuprofen Brill looks like and contents of the pack

Ibuprofen Brill film-coated 200 mg Tablets are white, about 9.5 mm, circular, film coated tablets, plain on both the sides. These are available in:

blister packs of 1, 6, 10, 12, 20, 28, 24, 30, 40, 48, 50, 60, 96 and 100 tablets

plastic bottles of 12, 20, 28, 24, 30, 40, 48, 50, 60, 96 and 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following name:

Denmark	Ibuprofen Bril 200mg fillovertrukne tabletter
Iceland	Ibuprofen Bril 200mg Filmuhúðaðar töflur
Poland	Ibuprofen Bristol Laboratories, 200 mg, tabletki powlekane
Sweden	Ibuprofen Bril, 200mg filmdragerad tablett

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