Package leaflet: Information for the patient

Ibuprofen B. Braun 200 mg solution for infusion
ibuprofen

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ibuprofen B. Braun is and what it is used for

Ibuprofen belongs to the group of medicines called “nonsteroidal anti-inflammatory drugs” or NSAIDs.

This medicine is used in adolescents and children from 20 kg bodyweight and 6 years of age and above for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible.

2. What you need to know before you are given Ibuprofen B. Braun

Ibuprofen B. Braun must not be given:

- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you have ever suffered from shortness of breath, have had asthma, skin rash, itchy runny nose or facial swelling, when previously taking ibuprofen, acetylsalicylic acid (aspirin) or other similiar painkillers (NSAIDs).
- If you have a condition which increases your tendency or active bleeding.
- If you have active, or history of two or more episodes of stomach ulcer or bleeding.
- If you have ever had bleeding or a tear in your stomach or gut when taking NSAIDs.
- If you are suffering from bleeding in the brain (cerebrovascular bleeding) or other active bleeding.
- If you suffer from severe kidney, liver or heart problems.
- If you are suffering from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake).
- If you are in the last three months of pregnancy.

Warnings and precautions

Talk to your doctor or nurse before using this medicine.

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. The recommended dose or duration of treatment should not be exceeded.

Skin reactions
Serious skin reactions have been reported in association with ibuprofen treatment. You should stop using Ibuprofen B. Braun 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 reaction. See section 4.

Discuss your treatment with your doctor before receiving Ibuprofen B. Braun:

- If you have heart problems including heart failure, chest pain (angina pectoris), or if you have had a heart attack, bypass surgery, poor circulation in the legs or feet due to narrow or blocked arteries (peripheral artery disease), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- If you have just had major surgery.
- If you have had or developed an ulcer, bleeding or perforation of the stomach or duodenum. In these cases, your doctor will consider of prescribing a protective medicine for the stomach.
- If you have asthma or other breathing disorder.
- If you have an infection - please see heading "Infections" below.
- If you have kidney disease or liver disease or use ibuprofen long-term, your doctor may need to carry out checks on a regular basis. Your doctor will tell you the frequency of these checks.
- If you are dehydrated e.g. due to diarrhoea, drink a lot of liquids and contact your doctor immediately as ibuprofen in this case could cause kidney failure as a result of dehydration.
- If you have Crohn's disease or ulcerative colitis because ibuprofen can worsen these conditions.
- If you observe any injuries, swelling or redness of the skin, trouble breathing (asphyxiation), immediately stop the treatment with the medicine and contact your doctor or nurse.
- If you have chickenpox (varicella) as complications can occur.
- If you have an inborn disorder of the porphyrin metabolism (e.g. acute intermittent porphyria).
- If you drink alcohol around the same time of receiving this medicine, side effects related to stomach, intestines and nervous system may be increased.
- If you suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders, you are at higher risk of allergic reactions. The allergic reactions may present as asthma attacks (so-called analgesic asthma), rapid swelling (Quincke´s oedema) or a rash.

Allergic reactions may occur with this medicine, mainly at the start of treatment. In this case, treatment should be discontinued.
There have been few cases of aseptic meningitis with the use of this medicine. The risk is greater if you suffer from an autoimmune disease called systemic lupus erythematosus and from related connective tissue diseases.
Blurred or diminished vision, blind spots in the field of vision and changes in colour vision have been reported with oral ibuprofen.
The use with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

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

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

In general the habitual use of several sort of painkillers can lead to lasting severe kidney problems.

On prolonged use of painkillers, headache may occur that must not be treated with increased doses of the medicine.

Ibuprofen can alter the following laboratory test:
- Bleeding time (may be prolonged 1 day after the end of the treatment)
- Blood-glucose values (may be decreased)
- Creatinine clearance (may be decreased)
- Hematocrit or hemoglobin (may be decreased)
- Blood urea nitrogen, serum creatinine and serum potassium (may be increased)
- Liver function test: increased transminase levels

Tell your doctor if you are going to undergo clinical tests and you are using or you have recently used ibuprofen.

The product is not recommended for children under 20 kg bodyweight or younger than 6 years.

There is a risk of renal impairment in dehydrated children and adolscents.

Other medicines and Ibuprofen B. Braun

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

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

- Other nonsteroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors (e.g. celecoxib) may increase the risk of gastrointestinal ulcers and bleeding due to an additive effect.
- Medicines that thin your blood or prevent clotting (anti-coagulants such as acetylsalicylic acid, warfarin, ticlopidine).
- Medicines used to treat heart failure (cardiac glycosides such as digoxin), or used to treat epilepsy (phenytoin) or used to treat depression (lithium), may increase their blood levels when taken with ibuprofen.
- A medicine used to treat certain types of cancers or rheumatism (methotrexate) taken at the same time as ibuprofen (within a range of 24 hours) can increase blood levels of methotrexate and its toxicity.
- A medicine used to terminate pregnancy (mifepristone).
- Class of drugs used as anti-depressants (SSRI-antidepressants, such as fluoxetine) may also increase the risk of bleeding of stomach and intestines.
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, angiotensin-II receptor antagonists such as losartan).
- Medicines used to treat inflammation (corticosteroids, such as hydrocortisone) because they increase the risk of ulcer or bleeding into stomach and intestines.
- Medicines used for urination (diuretics, such as bendroflumethiazide), as NSAIDs may reduce the effects of these medicines and it may increase the risk of kidney problems (using potassium sparing diuretics with ibuprofen can lead to high blood levels of potassium).
- Medicines containing probenecid and sulfinpyrazone may delay the excretion of ibuprofen.
- Medicines used to avoid transplant rejection (cyclosporin and tacrolimus) may increase the risk of kidney damage.

- Medicines used for diabetes (sulphonylureas, such as glibenclamide). Control of blood glucose values is recommended when these medicines are used together.
- Antibiotics of the quinolone group, such as ciprofloxacin due to an increased risk for developing fits (seizures).
- Medicines used for treatment of fungal infections (CYP2C9 inhibitors, such as voriconazole, fluconazole) can increase blood levels of ibuprofen.
- Medicine used for HIV infection (zidovudine) due to increased risk of blood accumulation in joints and bruises.
- Chronic alcohol consumption can increase the risk of significant side effects on stomach and intestines, including bleeding.
- A type of antibiotics (aminoglycosides). NSAIDs may decrease the excretion of aminoglycosides and increase their toxicity.
- Ginkgo biloba (a herbal medicine often used in dementia) may increase the risk of bleeding.

Some other medicines may also affect or be affected by the treatment with ibuprofen. You should therefore, always seek the advice of your doctor or nurse before you are given ibuprofen with other medicines.

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 nurse for advice before you are given this medicine.

Pregnancy

If you are pregnant, you will receive ibuprofen only if your doctor considers it absolutely necessary. You must not be given this medicine during 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 receive ibuprofen 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.

IV (intravenous) ibuprofen treatment should not exceed 3 days. 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

This medicine passes into breast milk but may be used during breast-feeding if it is used at the recommended dose and during the shortest possible time. However, if it is used at higher doses or for longer periods, your doctor may recommend to interrupt the breast feeding.

Fertility

Ibuprofen 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 to become pregnant.

Driving and using machines

No special precautions are necessary in short or acute treatments. However, during prolonged treatment, the occurrence of adverse effects, such as fatigue and dizziness may impair the ability to drive and / or use machinery. This is especially important when combined with alcohol.

Ibuprofen B. Braun contains sodium. This medicine contains 179 mg sodium (main component of cooking/table salt) per 50 ml. This is equivalent to 9 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Ibuprofen B. Braun is given

This medicine is prescribed to you only by a doctor and is only given to you by a doctor or nurse in an environment with appropriate equipment

The dose will be individually adjusted by your doctor, based on your weight and general condition.

For children and adolescents, ibuprofen is dosed depending on body weight or age, 5 to 10 mg/kg body weight as a single dose up to a maximum total daily dose of 30 mg/kg body weight:

Children weighing 20 kg – 29 kg (6-9 years old): 200 mg of ibuprofen up to 3 times a day not exceeding a maximum daily dose of 600 mg.

Children weighing 30 kg – 39 kg (10-11 years old): 200 mg of ibuprofen up to 4 times a day not exceeding a maximum daily dose of 800 mg.

Adolescents weighing 40 kg or more (12-17 years old): 200 mg to 400 mg of ibuprofen up to 3 times a day not exceeding a maximum daily dose of 1200 mg.

Not recommended for children under 20 kg bodyweight or below 6 years of age.

The respective dosing interval should be in line with the symptomatology and the maximum daily dose. The interval between doses should not be below 6 hours. The recommended maximum daily dose should never be exceeded.

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). Your doctor will also make sure that you have had enough fluids in order to minimize the risk of side effects to the kidney.

You should only receive this medicine if oral treatment is not possible. You must switch to oral treatment as soon as this is possible.

This medicinal product will only administered to you the shortest period needed. Treatment should not exceed 3 days.

Method of administration

For intravenous use. The solution should be administered by intravenous infusion over 30 minutes.

Inspect the solution before use. It should be discarded if any particulate matter is observed.

If you are given more Ibuprofen B. Braun than you should

As your dose is controlled by a doctor or nurse, it is unlikely that you will be given too much of this solution.

If you have been given more ibuprofen than you should, or if children have been given 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 can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion, ataxia and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

You might also suffer from low blood pressure, blueish colouration of the skin or mucous membranes (cyanosis), bleeding into stomach or intestines, as well as functional problems of the liver and kidneys.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects can be minimized by using the lowest effective dose for the shortest time possible to treat the symptoms. You can get one or more of the known side effects of NSAIDs (see below). If you experience any of these side effects, you should stop taking this medicine and consult a doctor as soon as possible.

The most commonly observed adverse events affect stomach and intestines. Peptic ulcers (stomach or intestinal ulcer), holes in the wall of the stomach or intestine (perforation) or bleeding from the stomach or intestines, sometimes fatal may occur. Indigestion, tarry stools, vomiting blood, inflammation of the oral mucosa with ulceration (ulcerative stomatitis), exacerbation of inflammation of large intestine (colitis) and Crohn's disease have been reported. Less frequently, stomach inflammation (gastritis) has been observed. Particularly the risk of bleeding into stomach and intestines occurring is dependent on the dose range and the duration of use.
Fluid accumulation in the tissues (oedema), high blood pressure and heart failure have been reported in association with NSAID treatment. Medicines like ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Very rarely severe allergic reactions (including infusion site reactions, anaphylactic shock) and serious skin side effects such as blistering reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell´s syndrome), erythema multiforme, and allergic inflammation of a blood vessel have been reported.

Exacerbation of inflammation related to infections (for example development of flesh-eating disease called necrotising fasciitis) coinciding with the use of NSAIDs has been described very rarely.

In exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection.

Very common side effects (may affect more than 1 in 10 people):

- Tiredness or sleeplessness, headache and dizziness.
- Heartburn, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and slight blood losses in stomach and intestines that may cause anaemia in exceptional cases.

Common side effects (may affect up to 1 in 10 people):

- Vertigo.
- Skin eruption.
- Pain and burning sensation at the administration site.
- Gastrointestinal ulcer, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn´s disease.

Uncommon side effects (may affect up to 1 in 100 people):

- Sleeping problems (insomnia), agitation, irritability or tiredness, anxiety and restlessness.
- Visual disturbances.
- Ringing or buzzing in the ears (tinnitus).
- Reduced production of urine and, particularly in patients with high blood pressure or kidney problems, symptoms due to kidney damage (nephrotic syndrome), interstitial nephritis that may be accompanied by acute kidney insufficiency.
- Urticaria, pruritus, purpura (including allergic purpura), skin rash.
- Allergic reactions with skin rashes and itching, as well as asthma attacks (possibly with drop of blood pressure).

Rare side effects (may affect up to 1 in 1,000 people):

- Reversible double vision (toxic amblyopia).
- Difficulty hearing.
- Narrowing of the oesophagus (blood vessels in gullet), complications of diverticula of the large bowel, unspecific haemorrhagic colitis, characterized by severe cramping and diarrhoea. If there is bleeding into stomach or intestines, it can cause anaemia.
- Damage of kidney tissue (papillary necrosis), particularly in long-term therapy, increased serum uric acid concentration in the blood.
- Yellowing of the skin or whites of the eyes, liver dysfunction, liver damage, particularly in long-term therapy, acute inflammation of the liver (hepatitis).
- Psychotic reactions, nervousness, irritability, confusion or disorientation and depression.
- Stiff neck.

Very rare side effects (may affect up to 1 in 10,000 people):

- Disorders of blood cell formation (anaemia, leukopenia, thrombocytopenia, pancytopenia, agranulocytosis). The first symptoms are: fever, sore throat, surface mouth ulcers, flu-like symptoms, severe fatigue, nasal and skin bleeding.
- Rapid heartbeat (palpitations), heart failure, myocardial infarction.
- Arterial hypertension
- Aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or confusion). Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed.
- Inflammation of the gullet (oesophagus) or pancreas, narrowing of the bowel.
- Hair loss
- Sensitivity to light and allergic vasculitis
- Asthma, difficulty breathing (bronchospasm), shortness of breath and wheezing.
- An autoimmune disease called systemic lupus erythematosus, severe allergic reaction (face oedema, swelling of the tongue, swelling of the throat with constriction of the airways, difficulty breathing, rapid heartbeat and decreased blood pressure and life threatening shock).

Not known side effects (frequency cannot be estimated from the available data):

- Liver insufficiency.
- Injection site reactions such as swelling, bruising or bleeding.
- 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 Ibuprofen B. Braun if you develop these symptoms and seek medical attention immediately. See also section 2.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen B. Braun

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

This medicinal product does not require any special storage conditions.

The product should be used immediately after opening. Do not use this medicine if you notice any particles.

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

6. Contents of the pack and other information

What Ibuprofen B. Braun contains
- The active substance is ibuprofen. Each ml of solution contains 4 mg of ibuprofen. Each 50 ml bottle contains 200 mg of ibuprofen.
- The other ingredients are L-arginine, sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injection.

What Ibuprofen B. Braun looks like and contents of the pack

Clear and colourless to pale yellow solution for infusion, without any particulate matter.

The solution is contained in closed LDPE bottles of 50 ml with Twincap in packs of 10 bottles and 20 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
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Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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

ES	Ibuprofeno B. Braun pediátrico 200 mg solución para perfusión
AT	Ibuprofen B. Braun 200 mg Paed Infusionslösung
BE	Ibuprofen B. Braun 200 mg oplossing voor infusie
CZ	Ibuprofen B. Braun
DE	Ibuprofen B. Braun 200 mg Infusionslösung
DK	Ibuprofen B. Braun
EE	Ibuprofen B. Braun
FI	Ibuprofen B. Braun 200 mg infuusioneste, liuos
FR	Ibuprofène B. Braun paediatric 200 mg solution pour perfusion
HU	Ibuprofen B. Braun paediatric 200 mg oldatos infúzió
IE	Ibuprofen B. Braun 200 mg solution for infusion
IT	Ibuprofene B. Braun Melsungen
LU	Ibuprofen B. Braun paediatric 200 mg solution pour perfusion
LV	Ibuprofen B. Braun 200 mg šķīdums infūzijām
NO	Ibuprofen B. Braun 200 mg infusjonsvæske, oppløsning
PL	Ibuprofen B. Braun
RO	Ibuprofen B. Braun paediatric 200 mg soluţie perfuzabilă
SE	Ibuprofen B. Braun 200 mg infusionsvätska, lösning
SI	Ibuprofen B. Braun za otroke 200 mg raztopina za infundiranje
SK	Ibuprofen B. Braun 200 mg
UK	Ibuprofen 200 mg Solution for Infusion

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