

Package leaflet: Information for the user

Brufen 200 mg Effervescent Granules

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 have 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

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

The full name of your medicine is Brufen 200 mg Effervescent Granules. In this leaflet the shorter name Brufen is used.

1. What Brufen is and what it is used for

Brufen belongs to a group of medicines called ‘non-steroidal anti-inflammatory drugs’ or NSAIDs. Each sachet of medicine contains 200 mg of ibuprofen.

This medicine is used:

- to relieve pain in conditions such as toothache, period pain and headache
- to reduce fever (high temperature) and pain when you have the common cold.

It can be used in adults and children over 30 kg in body weight (over 8 years old).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Brufen

Do not take Brufen if:

- you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)

- you have ever had an allergic reaction to ibuprofen, acetylsalicylic acid (e.g. Aspirin) or other NSAIDs - the signs include a reddening or rash of the skin, swollen face or lips or shortness of breath
- you have (or have had two or more episodes of) a stomach ulcer or bleeding of the stomach
- you have a history of gastrointestinal bleeding or perforation related to previous NSAID therapy
- you have severe liver or kidney problems
- you have severe heart failure or coronary heart disease
- you have active bleeding or an illness that may make you more likely to bleed
- you have disturbances in the formation of blood cells of unknown cause
- you are very dehydrated - this may be due to being sick, diarrhoea or not drinking enough fluid
- you are in the last 3 months of pregnancy. See ‘Pregnancy, breast-feeding and fertility’ below for more information.

Do not take Brufen if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Brufen if you:

- have Systemic Lupus Erythematosus (SLE, an illness that affects connective tissue, including your joints and skin) or other autoimmune diseases because of increased risk of aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or disorientation)
- have disturbances in the formation of blood cells
- have problems with normal blood clotting mechanism
- have ever had stomach or gut problems (such as ulcerative colitis or Crohn’s disease)
- have kidney or liver problems
- have recently had a major operation
- have had allergic reactions to other medicines for other conditions in the past
- have hay fever, nasal polyps (loss of smell, runny or blocked nose) or breathing problems, because there is also an increased risk of allergic reactions for you, which may present as asthma attacks, swelling of the skin or hives
- are elderly (over 65 years) - this is because you may be more likely to get serious side effects
- have chicken pox or shingles (varicella)
- are dehydrated
- have ever had asthma
- are taking other pain relieving drugs regularly - particularly if you are physically active which can lead to a loss of salt or dehydration.
- if you have an infection - please see heading “Infections” below.

Talk to your doctor or pharmacist before taking Brufen if any of the above apply to you.

Heart attack and stroke

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 Brufen 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.

Renal effects

There is a risk of kidney damage in dehydrated children, adolescents and elderly.

Infections

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

Skin reactions

Serious skin reactions have been reported in association with Brufen treatment. You should stop taking Brufen 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.

Do not take more than the recommended dose of this medicine.

Also, do not take this medicine for longer than recommended in this leaflet (3 days).

General information on prolonged use of painkillers

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.

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

Consult a doctor before using Brufen if any above mentioned conditions concern you.

Children

This medicine should not be given to children with a body weight of less than 30 kg (under 8 years old).

Other medicines and Brufen

Brufen 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)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of Brufen.

You should therefore always seek the advice of your doctor or pharmacist before you use Brufen with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell them if you are taking:

acetylsalicylic acid (e.g. Aspirin) - do not use Brufen if you are taking more than 75 mg of acetylsalicylic acid (e.g. Aspirin) per day.	since this may increase the risk of gastrointestinal ulcers or bleeding
other NSAIDs (anti-inflammatories and analgesics) including Cox-2 inhibitors (such as celecoxib)	since this may increase the risk of gastrointestinal ulcers or bleeding
other medicines containing ibuprofen, such as those you can buy without a prescription	since this may increase the risk of gastrointestinal ulcers or bleeding
acetylsalicylic acid (e.g. Aspirin), Low dose - if you are on low-dose acetylsalicylic acid (up to 75 mg daily) speak to your doctor or pharmacist before you take Brufen.	since the blood-thinning effect may be impaired
medicines for heart problems - such as digoxin	since the effect of digoxin may be enhanced
corticosteroids - used for inflammatory conditions	since this may increase the risk of gastrointestinal ulcers or bleeding
medicines to stop blood clots - such as acetylsalicylic acid (e.g. Aspirin) or ticlopidine	since this may increase the risk of bleeding
medicines for thinning the blood (such as warfarin)	since ibuprofen may enhance the effects of these medicines
phenytoin (for epilepsy)	since the effect of phenytoin may be enhanced
selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, used for depression	as these may increase the risk of gastrointestinal bleeding
lithium - used for some forms of depression	since the effect of lithium may be enhanced
probenecid and sulfinpyrazones (medicines for gout)	since the excretion of ibuprofen may be delayed
medicines for high blood pressure - including ACE-inhibitors (such as captopril), beta blockers (such as atenolol) or angiotensin-II receptor antagonists (such as losartan) and diuretics (water	since ibuprofen may diminish the effects of these medicines and there could be a possible increased risk for the kidney

tablets)	
Potassium-sparing diuretics	since this may lead to hyperkalaemia
methotrexate - used for some cancers or rheumatism	since the effect of methotrexate may be enhanced
medicines that suppress your immune system - such as ciclosporin or tacrolimus	since kidney damage may occur
zidovudine - used for HIV or AIDS	since the use of Brufen may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling in HIV (+) haemophiliacs
medicines for diabetes - such as glibenclamide	interactions may be possible
quinolone antibiotics for infection (such as ciprofloxacin)	since the risk for convulsions may be increased
some antibiotics for infections, like aminoglycosides (such as gentamicin)	since their elimination may be decreased
cholestyramine - used to lower cholesterol	since the absorption of ibuprofen may be reduced. Do not take Brufen two hours before or after you take cholestyramine.
mifepristone - used for medical termination of pregnancy	since a decrease in the effect of mifepristone may occur
Ginkgo biloba - a herbal medicine often used in dementia	There is a chance you may bleed more easily if you are taking this with Brufen.
voriconazole or fluconazole - used for fungal infections	since the risk of higher concentration of ibuprofen in the blood is increased

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Brufen.

Brufen with alcohol

If you drink alcohol while taking this medicine you may be more likely to get side effects.

Pregnancy, breast-feeding and fertility

- Do not take this medicine if you are in the last 3 months of pregnancy.
- Talk to your doctor or pharmacist before taking this medicine if you are in the first 6 months of pregnancy or you are breast-feeding. You should only take this medicine on the advice of your doctor.

Brufen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

This medicine may make you feel dizzy or sleepy. If this happens, do not drive or use any tools or machines. Also, do not do anything else where you need to be alert.

Brufen contains sucrose and sodium

Sucrose

Sucrose is a sugar. Brufen contains 1111 mg sucrose per sachet. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Sodium

Brufen contains 66 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 3.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Brufen

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

The product is intended for short-term use only. 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).

How much to take

Adults and young people over 40 kg body weight (over 12 years old):

- Take one or two sachets (200 – 400 mg ibuprofen) every 4-6 hours, as required.

More than 400mg at a time does not give a better analgesic effect.

Do not take more than a total of 6 sachets (1200mg) in any 24 hours.

Children over 30 kg body weight (from 8 to 12 years old):

If you are giving this medicine to a child, you should use the following dosing instructions:

Body weight of child	Recommended dose	How often?
Children 30 kg to 39 kg (8-12 years)	1 sachet (200 mg ibuprofen)	<ul style="list-style-type: none">• Doses should be given every 6-8 hours, if required.• Do not take more than 3 sachets (up to 600 mg ibuprofen) in any 24 hours.

- The recommended dose of ibuprofen each day is 20 mg per kg of body weight.
 - This is taken in 3 separate doses throughout the day.
 - Please see the table above.

Do not take more than a total of 600 mg (3 sachets) in any 24 hours.

Children under 30 kg body weight (under 8 years old):

This medicine should not be given to children with a body weight of less than 30 kg (under 8 years old).

Taking this medicine

In order to achieve a faster onset of action, the dose may be taken on an empty stomach. If you have a sensitive stomach, take this medicine with or just after food.

- Empty the granules from one sachet into a small glass of water (about 125 ml).
- Make sure that you use all of the granules in the sachet.
- Stir the medicine until it stops bubbling and the granules have dissolved - this will make an orange flavoured, fizzy drink.
- If you use more than one sachet at one time, you should use more water. Use about 125 ml for each sachet of medicine.

How long to continue treatment

If you need to take Brufen for more than 3 days or if your symptoms worsen, consult your doctor.

If you take more Brufen than you should

If you have taken more Brufen 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. Take the medicine pack with you.

The symptoms can include nausea, stomach pain, vomiting (may be blood in it), 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, cold body feeling, and breathing problems have been reported.

If you forget to take Brufen

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for your next dose, skip the missed 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, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop taking this medicine and see your doctor straightaway if you notice any of the following serious side effects - you may need urgent medical attention:

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

- pass blood in your faeces (stools/motions)

- pass black tarry stools
- vomit any blood or dark particles that look like coffee grounds

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

- hives
- swelling of the face, tongue or throat
- difficulty swallowing or breathing

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

- severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle; this may occur in exceptional cases during chicken pox

Not known (we do not know how often these happen):

- 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 Brufen if you develop these symptoms and seek medical attention immediately. See also section 2.

Stop taking this medicine and see your doctor straightaway if you notice any of the side effects above.

Stop taking this medicine and tell your doctor if you notice any of the following:

- indigestion or heartburn
- abdominal (stomach) pains or other abnormal stomach symptoms.

Stop taking this medicine and tell your doctor if you notice any of the side effects above.

Other side effects

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

- feeling dizzy or tired
- feeling drowsy
- agitation, irritability
- loss of appetite, diarrhoea, feeling sick, being sick, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this
- rash

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

- feeling anxious
- difficulty sleeping, hives, itching
- skin becomes sensitive to light
- visual disturbances, hearing problems
- ringing in ears (tinnitus)
- spinning sensation, loss of balance (vertigo)
- hepatitis, yellowing of your skin or eyes

- sneezing, blocked, itchy or runny nose (rhinitis)
- mouth ulcer
- stomach ulcer, inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- pins and needles
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- reduced kidney function

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

- loss of vision
- reduced liver function
- feeling depressed or confused
- hallucinations
- fluid retention (oedema)
- Lupus erythematosus syndrome or SLE (an illness that affects connective tissue, including your joints and skin)
- a brain infection called ‘non-bacterial meningitis’
- changes in blood count - the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, feeling very tired, bleeding from the nose and the skin

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

- unpleasant awareness of heart beat, heart failure, heart attack, high blood pressure, acute oedema in the lung
- liver failure
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as ‘Stevens-Johnson syndrome’, ‘exfoliative dermatitis’ or ‘erythema multiforme’. This can get even more severe, where the blisters get larger and spread out and parts of the skin may slough off (toxic epidermal necrolysis). There may also be severe infection with destruction (necrosis) of skin, subcutaneous tissue and muscle.
- prolonged bleeding time
- inflammation of the oesophagus, intestinal strictures
- hair loss (alopecia)

Not known (we do not know how often these happen):

- worsening of ulcerative colitis or Crohn’s disease
- burning feeling in the throat or mouth - this may happen briefly after taking this medicine.

Medicines such as Brufen may be associated with a small increased risk of heart attack (‘myocardial infarction’) 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 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 Brufen

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

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Do not use after the expiry date stated on the sachet and carton. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Brufen contains

- The active substance is ibuprofen. Each sachet of medicine contains 200 mg of ibuprofen.
- The other ingredients are croscarmellose sodium, malic acid, microcrystalline cellulose, saccharin sodium, sucrose, povidone, orange flavour, sodium laurilsulfate, sodium hydrogen carbonate and sodium carbonate, anhydrous.

What Brufen looks like and contents of the pack

Brufen 200 mg Effervescent Granules are a white powder with an orange flavour. Your medicine will be in a sachet.

Each carton contains 12, 20 or 30 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Mylan IRE Healthcare Limited,
Unit 35/36,
Grange Parade,
Baldoyle Industrial Estate,
Dublin 13.

Manufacturer:

AbbVie S.r.l. S.R. 148 Pontina km 52 snc, 04011 Campoverde di Aprilia (LT) Italy

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

United Kingdom BRUFEN 200 mg Effervescent Granules

Austria	BRUFEN 200 mg Brausegranulat
Bulgaria	BRUFEN 200 mg Ефервесцентна Гранули
Estonia	BRUFEN
Ireland	BRUFEN 200 mg Effervescent Granules
Italy	Froben Dolore e Febbre
Latvia	BRUFEN 200 mg putojošās granulas
Lithuania	BRUFEN 200 mg Šnypščiosios granulės
Slovenia	Brufen Gran 200 mg šumeča zrnca.

This leaflet was last revised in September 2020