

Package leaflet: Information for the user

Brufen 400 mg effervescent Granules

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 texts in brackets are only applicable for prescription versions.

[Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.]

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.]

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.

1. Keep this leaflet. You may need to read it again.
2. Ask your pharmacist if you need more information or advice.
3. 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.
4. You must talk to a doctor if you do not feel better or if you feel worse after 3 days with fever and 5 days with pain.

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

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. One sachet of medicine contains 400 mg of ibuprofen.

This medicine is for short-term use in adults and adolescents over 12 years (40 kg and above)

- to relieve mild to moderate pain such as headache and toothache,
- to relieve period pain
- to reduce fever (high temperature)

2. What you need to know before you take Brufen

Do not give/take Brufen:

- to children younger than 12 years of age
- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had an allergic reaction to ibuprofen, acetylsalicylic acid or other NSAIDs - the signs include a reddening or rash of the skin, swollen face or lips, runny nose, wheezing or shortness of breath
- if you have (or have had two or more episodes of) a stomach/duodenal ulcer (peptic ulcer) or bleeding
- if you have ever had bleeding or a tear in your stomach or gut when taking NSAIDs
- if you have severe liver or kidney problems
- if you have severe heart failure or coronary heart disease
- if you are suffering from bleeding on the brain (cerebrovascular bleeding) or other active bleeding
- if you have an illness that may make you more likely to bleed
- if you are suffering from significant dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- if 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 applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Brufen:

- 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, chronic swelling of nasal mucosa, sinuses, adenoids, or chronic obstructive respiratory disorders, because the risk for developing narrowing of the airways with difficulty in breathing (bronchospasm) is greater. There is also an increased risk of allergic reactions occurring, which may present as asthma attacks, swelling of the skin or hives.
- if you have ever had asthma
- 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 planning a pregnancy (see "Pregnancy, breast-feeding and fertility" below for more information)
- if you are breast-feeding
- if you have chickenpox
- if you have Systemic Lupus Erythematosus (SLE) or other autoimmune diseases as there may be an increased risk of aseptic meningitis
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria)
- if you have an infection - please see heading "Infections" below.

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

Patients who have previously had gastrointestinal tract problems, especially elderly patients, should contact a doctor in the event of abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of treatment.

Treatment must be stopped and a doctor consulted when gastrointestinal bleeding or ulceration occurs during treatment with Brufen.

Elderly

Elderly people should be aware of their increased risk of adverse events, especially bleeding and perforation in the digestive tract, which may be fatal.

Lowest effective dose

The lowest effective dose should always be used to minimise the risk for adverse events. Using a higher dose than recommended may cause serious risks.

With Brufen, there is a risk of serious side effects. Please refer to section 4 for information on what action to take if this occurs.

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.

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 immediately <Brufen> and contact immediately your doctor or medical emergencies if you notice any of these signs.

Renal effects

There is a risk of kidney damage especially in dehydrated adolescents and the elderly.

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

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.

Children under 12 years of age

This medicine should not be given to children under 12 years of age.

Other medicines and Brufen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Brufen can affect the way some other medicines work. Also, some other medicines can affect the way Brufen works.

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

- acetylsalicylic acid
- Do not use this medicine if you are taking other NSAID painkillers.
- other medicines containing ibuprofen, such as those you can buy without a prescription
- medicines for heart problems - such as digoxin
- medicines for diabetes (so-called sulphonylureas)
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that suppress your immune system - such as ciclosporin or tacrolimus
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- diuretics (water tablets)
- steroids - used for inflammatory conditions
- selective serotonin reuptake inhibitors (SSRIs) - used for depression
- some antibiotics for infections - including aminoglycosides and quinolones
- zidovudine - used for HIV or AIDS
- methotrexate - used for some cancers or rheumatism
- cholestyramine - used to lower cholesterol
- lithium - used for some forms of depression
- voriconazole or fluconazole - used for fungal infections
- mifepristone - used for medical termination of pregnancy
- Ginkgo biloba – a herbal medicine often used in dementia

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

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.

Brufen with alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

- Do not take this medicine 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 Brufen during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Brufen can cause kidney problems in

your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Ibuprofen is excreted in breast milk but is not likely to have an effect on the infant when used for short-term treatment. Consult a doctor if you use Brufen more often than temporarily while breast-feeding.

Fertility

Ibuprofen belongs to a group of medicines (NSAIDs) which may impair the 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 or pharmacist before taking this medicine if you are having problems getting pregnant.

Driving and using machines

This medicine may make you feel dizzy or sleepy. This particularly applies in interaction with alcohol. If this happens, do not drive or use any tools or machines. Do not do anything else where you need to be alert.

Brufen contains sucrose

Sucrose is a sugar. Brufen contains 2222 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.

Brufen contains sodium

Brufen contains 131 mg sodium (main component of cooking/table salt) in each sachet. This is equivalent to 6.6% 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 doctor or 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 long to continue treatment

If symptoms worsen, or do not improve within 3 days with fever and 5 days with pain consult your doctor.

If, in adolescents, aged 12-18 years, symptoms worsen, or if this product is required for more than 3 days, a doctor should be consulted.

How much to take

Adults and adolescents over 12 years of age (40 kg or above)

Take one sachet (400 mg) as a single dose or up to 3 times a day with an interval of 4 to 6 hours.

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

Do not take more than a total of 3 sachets (1200 mg) in any 24 hours.

People with liver or kidney problems

If you have liver or kidney problems, your doctor will tell you the correct dose to take. This will be the lowest dose possible.

The elderly (over 65 years)

If you are elderly, your doctor will tell you the correct dose to take. This will be the lowest dose possible.

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 the dose with 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 and do not divide the content to make several doses.
- Stir the medicine until it stops bubbling and the granules have dissolved - this will make an orange flavoured, fizzy drink. Drink immediately.

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 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, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported.

If you usually take painkillers, especially combinations of different substances with painkilling effect, you may damage your kidneys permanently, with the risk of kidney failure. This risk may be increased if you are dehydrated. Therefore you should avoid excessive use of any painkillers.

If you use painkillers for a long time, this can cause headaches, which should not be treated with more painkillers. If you think this applies to you, talk to your doctor or pharmacist.

If you forget to take Brufen

- If you forget a dose, take it as soon as you remember. 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 straight away 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):

- Black tarry stools (faeces/motions) or blood in the stools
- Vomiting any blood or dark particles that look like coffee grounds

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

Swelling of the face, tongue or throat (larynx) which can cause great difficulty in breathing (angioedema)

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

- Disorders of blood cell formation (agranulocytosis, with symptoms like fever, sore throat, surface mouth ulcers, flu-like symptoms, severe fatigue, nasal and skin bleeding). Your doctor will need to check the amount of blood cells in your blood.
- 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

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

- Reddish non-elevated, target-like or circular patches on the trunk, 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]. Exceptionally, serious infections of the skin in case of chicken pox. When an NSAID is used, an infection-related inflammation of the skin could develop or become more severe (e.g. a condition such as necrotising fasciitis may develop characterized by intense pain, high fever, swollen and hot skin, blistering, necrosis). If signs of an infection of the skin occur or get worse during use of ibuprofen you are recommended to see your doctor immediately.

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

- 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). Stop using <Brufen> if you develop these symptoms and seek medical attention immediately. See also section 2.
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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

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

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

- Heartburn, abdominal pain, indigestion
- Skin rash

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

- Blurred vision or other eye problems
- Hypersensitivity reactions such as hives, itching, small bruises in skin and mucous membranes, asthma attacks (sometimes with low blood pressure)
- Sensitivity to light

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

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):

- Disturbances in the digestive tract, such as diarrhoea, feeling sick, vomiting, wind, constipation
- Headache, sleepiness, dizziness, agitation, insomnia, irritability, vertigo
- Microscopic bleeding from the intestine which may result in anemia
- Tiredness

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

- Digestive tract ulcer with or without perforation
- Complications of diverticula of the large bowel (perforation or fistula)
- Kidney problems including inflammation of the kidneys and kidney failure
- Mouth ulcers and inflammation
- Inflammation of the stomach lining
- Runny nose
- Difficulty breathing (bronchospasm)
- Anxiety
- Pins and needles
- Difficulty hearing
- Asthma
- Acute inflammation of the liver, yellowish discolouration of the skin or whites of the eyes, liver dysfunction

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

- Depression, confusion, hallucinations
- Lupus erythematosus syndrome
- Inflammation of the brain membrane (without bacterial infection)
- Liver damage
- Oedema

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

- Unpleasant awareness of heart beat, heart failure, heart attack or high blood pressure
- Ringing or buzzing in the ears
- Inflammation of the oesophagus or pancreas
- Narrowing of the bowel
- Liver failure
- Damage of the kidney tissue
- Hair loss

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

- Burning feeling in the throat or mouth, this may happen briefly after taking this medicine
 - Worsening of ulcers in the large intestine and Crohn's disease (bowel disease)

The following side effects have also been reported with other NSAIDs:

- High blood pressure or heart failure
- A small increased risk of heart attack or stroke.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

To be completed nationally

5. How to store Brufen

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

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is 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 protect the environment.

6. Contents of the pack and other information

What Brufen contains

- The active substance is ibuprofen. One sachet contains: ibuprofen 400 mg.
- The other ingredients are croscarmellose sodium, malic acid, microcrystalline cellulose, saccharin sodium, sucrose, povidone, orange flavour, sodium laurilsulfate, sodium hydrogen carbonate and anhydrous sodium carbonate.

What Brufen looks like and contents of the pack

Brufen is a white powder with an orange flavour. Your medicine will be contained in sachets.

Each pack contains 12, 15, 20, 30 or 40 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<To be completed nationally>

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:

Sweden	Brufen 400 mg brusgranulat
Austria	Neobrufen 400 mg Brausegranulat
Belgium	Brufen Granules 400 mg
Estonia	Brumare
Hungary	Brufen 400 mg pezsgőgranulátum
Italy	FRoben DOLORE E INFIAMMAZIONE
Lithuania	Brumare 400 mg šnypščiosios granulės

Luxembourg	Brufen Granules 400 mg
Latvia	Brumare 400 mg putojošās granulas
Portugal	Brufen 400 mg granulado efervescente
Slovakia	Brufen INSTANT 400 mg.

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