

PACKAGE LEAFLET: INFORMATION FOR THE USER

BRUFEN

400 mg Effervescent Granules

IBUPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

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

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

It can be used in adults and adolescents over 12 years (40 kg and above).

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 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 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
- if you have inherited a disorder of the red blood pigment haemoglobin (porphyria)

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

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

Talk to a doctor or pharmacist before taking this medicine if you have heart problems, have had a stroke or if you think that you are likely to get these conditions. This is, for example, if you have high blood pressure, diabetes, high cholesterol levels or if you smoke.

This medicine may lead to a small increased risk of heart attack or stroke. This increased risk is more likely with high doses and long-term treatment.

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

Renal effects

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

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.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- 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 to stop blood clots - such as acetylsalicylic acid warfarin or ticlopidine
- medicines that suppress your immune system - such as ciclosporin or tacrolimus
- medicines for high blood pressure - including ACE-inhibitors (such as captopril), beta blockers or angiotensin-II receptor antagonists
- 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
- 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.

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 Pregnancy

- 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 planning a pregnancy, or are in the first 6 months of pregnancy. You should only take this medicine on the advice of your doctor.

Breast -feeding

Ibuprofen is excreted in breast milk but is not likely to have an effect on the infant. 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. 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. 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 100 mg sodium per sachet. This should be taken into account if you are on a low sodium diet. You may need to have less sodium in your diet because of the sodium in this medicine.

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. You should take the lowest dose for the shortest time necessary to relieve your symptoms.

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.
- Stir the medicine until it stops bubbling and the granules have dissolved - this will make an orange flavoured, fizzy drink.

If you take more Brufen than you should

If you have taken more of this medicine than you should, contact a doctor or go to the nearest hospital straight away. Take the medicine pack with you.

The signs of an overdose can include: feeling sick, stomach pain, being sick (may have blood in it), headache, ringing in the ears, confusion and shaky eye movement. At high doses, there may be loss of consciousness, fits (mainly in children), feeling weak or dizzy, blood in the urine, feeling cold and breathing problems.

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

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 syndrome). 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.
- 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.

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

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

- Blurred vision or other eye problems
- Hypersensitivity reactions such as hives, skin rash, itching, 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)
- 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
- 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
- failure
- Inflammation of the brain membrane (without bacterial infection)
- Damage of the kidney tissue
- Kidney problems including inflammation of the kidneys and kidney failure
- Hair loss

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

- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BRUFEN

Keep 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 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 malic acid, 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 sachets.

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