

Package leaflet: Information for the user

Brufen® Retard 800mg Prolonged Release Tablets
ibuprofen

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Brufen is 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 Retard 800mg prolonged release tablets**. 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 anti-inflammatory pain killers.

The active ingredient in Brufen is ibuprofen and each tablet contains 800mg of ibuprofen in a sustained release formulation. This is designed to release ibuprofen gradually into your blood stream throughout the day.

It can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendonitis, tenosynovitis, lower back pain, sprains and strains.

Brufen can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

2. What you need to know before you take Brufen

Do not take Brufen tablets

- if you are allergic to ibuprofen or any of the ingredients of this medicine (listed in Section 6)
- if you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)
- if you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past

- if you suffer from severe heart failure, liver failure or kidney failure
- have a condition which increases your tendency to bleeding
- if you are sensitive (allergic) or previously had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers
- if you are in the third trimester (last three months) of pregnancy

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Brufen

- if you have, or previously suffered from bronchial asthma, chronic rhinitis or allergic diseases
- if you suffer from liver, kidney or heart disease
- if you suffer from high blood pressure (hypertension)
- if you are elderly - elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- if you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint
- if you are dehydrated - there is a risk of renal impairment in dehydrated children, adolescents and the elderly
- if you have a condition which increases your tendency to bleeding or have bleeding in the skull – please see above
- if you have lupus or a connective tissue disease (autoimmune diseases affecting connective tissue)
- if you have an infection – please see heading “Infections” below
- During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

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.

Heart attack and stroke

Anti-inflammatory/pain-killer medicines like Brufen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor, pharmacist or nurse before taking Brufen if you:

- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or 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

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.

Allergic reactions

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 taking Brufen and contact immediately your doctor or medical emergency department if you notice any of these signs.

Children and adolescents

Brufen is not recommended for children.

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 may affect or be affected by some medicines.

For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, heparin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin-II receptor antagonists such as losartan)

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

In particular you should tell your doctor or pharmacist if you are taking any of the following medicines in addition to those mentioned above:

- any medicines used to treat high blood pressure (see above)
- any medicines to treat heart conditions (e.g. diuretics such as bendroflumethiazide or furosemide or cardiac glycosides such as digoxin)
- any anti-coagulants or anti-platelet medicines (see above)
- lithium or selective serotonin reuptake inhibitors (SSRIs) (used to treat depression)
- a medicine called zidovudine (an anti-viral drug)
- a medicine called methotrexate (used to treat some forms of cancer)
- medicines called cyclosporin or tacrolimus (immunosuppressants used following organ transplant or in autoimmune conditions such as psoriasis, eczema)
- any other NSAIDs or anti-inflammatory pain killers, including aspirin and the group of drugs known as COX-2 inhibitors such as celecoxib and lumiracoxib
- any corticosteroids (e.g. hydrocortisone, betamethasone, prednisolone, used to treat inflammatory conditions)

- a certain type of antibiotic, known as quinolone antibiotics (e.g. ciprofloxacin and levofloxacin)
- a certain type of antibiotic known as aminoglycosides
- mifepristone (used for the medical termination of pregnancy)
- any oral medicines used to treat diabetes (e.g. metformin, or any sulphonylurea medicines)
- a herbal remedy called ginkgo bilboa (there is a chance that you may bleed more easily if you are taking ibuprofen and ginkgo biloba at the same time).
- cholestyramine (used to treat high cholesterol levels)
- voriconazole or fluconazole (anti-fungal drugs)

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 ibuprofen 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 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. 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.

Brufen is not recommended while breastfeeding.

Brufen 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 becoming pregnant.

Driving and using machines

Medicines such as Brufen may cause dizziness, drowsiness, tiredness and problems with vision. If affected, you should not drive or operate machines. Also you should not do anything else where you need to be alert. This particularly applies in combination with alcohol.

3. How to take Brufen

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

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).

Take Brufen with plenty of fluid. You should swallow the tablets whole without chewing, breaking, crushing or sucking them.

It is recommended that patients with sensitive stomachs take ibuprofen with food.

The recommended dose is

Adults and adolescents over 12 years ($\geq 40\text{kg}$): - The usual dose is two tablets taken as a single dose each day. The tablets are best taken in the early evening, well before retiring to bed.

In severe or acute conditions, your doctor may prescribe one extra tablet to be taken each morning in addition to the evening dose.

Elderly – Refer to adult dosing. If you have liver or kidney problems however, your dose may need to be modified in which case you should contact your doctor for advice.

Children - Brufen Retard is not suitable for children under 12 years of age.

Avoid prolonged use of any painkillers as these may result in headaches that should not be treated with increased doses of Brufen. Tell your doctor if this occurs.

If you take more Brufen than you should.

If you take 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.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), headaches, 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 forget to take Brufen

- take them as soon as you remember. However, if it is almost time for your next dose skip the missed dose.
- do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist. You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

Serious side effects

Stop taking Brufen and seek medical attention immediately if you notice any of the following symptoms:

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

- signs of bleeding from the stomach or gut such as passing blood in your faeces (stools/motions), passing black tarry stools or 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 swallowing and breathing (angioedema)

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

- rapid heartbeat, severe fall in blood pressure or life threatening shock

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).
- 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):

- 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 (acute generalised exanthematous pustulosis).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Stop taking this medicine and seek medical attention immediately 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):

- 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):

- rash
- feeling dizzy or tired
- 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.

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

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives, itching

- skin becomes sensitive to light
- visual disturbances, hearing problems
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- hepatitis, yellowing of your skin or eyes, reduced liver function
- reduced kidney function, inflammation of the kidneys, kidney failure
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- hypersensitivity reactions such as unexplained wheezing, shortness of breath, skin rash, itching or bruising

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

- feeling depressed or confused
- fluid retention (oedema)
- a brain infection called 'non-bacterial meningitis'
- loss of vision
- 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
- reduction in blood cells (anaemia)

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

- heart failure, heart attack, high blood pressure
- liver failure
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis' or 'erythema multiforme'.

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

- prolonged bleeding time
- worsening of ulcers in the large intestine (colitis) or Crohn's Disease (bowel disease)

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

- high blood pressure or heart failure
- worsening of ulcers in the large intestine and Crohn's disease (bowel disease)
- a small increased risk of heart attack or stroke.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 use this medicine after the expiry date which is stated on the carton and blister after 'EXP:'. The expiry date refers to the last day of that month.

Do not store above 25°C. The tablets should be kept in their original packaging in order to protect from moisture.

If your doctor decides to stop your treatment, return any leftover tablets to your pharmacist. Only keep the tablets if your doctor tells you to.

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 in Brufen is ibuprofen. Each tablet contains 800 mg ibuprofen in a prolonged release formulation, designed to release ibuprofen gradually into your blood stream throughout the day.
- the other ingredients are: xanthan gum, povidone, hypromellose, stearic acid, colloidal anhydrous silica, talc, Opaspray white M-1-7111B (containing hypromellose and titanium dioxide (E171)).

What Brufen looks like and the contents of the pack

- The tablets are white, pillow-shaped and film-coated.
- The tablets are available in blister packs.

Each pack contains 60 tablets

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Viartis Healthcare Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland

Manufacturer:

FAMAR A.V.E. Anthoussa Plant
Anthoussa Avenue 7
15349 Anthoussa Attiki
Greece.

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