

Package Leaflet: Information for the User
BRUFEN® RETARD 800 mg TABLETS
 (ibuprofen)

Your medicine is known as BRUFEN® RETARD 800 mg TABLETS but will be referred to as Brufen Retard throughout the following leaflet.



IMPORTANT INFORMATION

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet as you may need to read it again
- This leaflet provides a summary of the information currently available about Brufen Retard
- For further information or advice ask your doctor or pharmacist
- This medicine is for you only and should never be given to anyone else, even if they appear to have the same symptoms as you
- Tell your doctor or pharmacist if you experience any side effects

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1. WHAT IS BRUFEN RETARD & WHAT IS IT USED FOR?

Brufen Retard belongs to a group of medicines called anti-inflammatory pain killers. 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, tendinitis, tenosynovitis, lower back pain, sprains and strains.

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

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

2. WHAT SHOULD YOU KNOW BEFORE TAKING BRUFEN RETARD?



If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any Brufen Retard:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Brufen Retard 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.
- Are you sensitive (allergic) to any of the ingredients in the tablets? These are listed in Section 6.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint?
Do not take Brufen Retard 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.
- Do you have a condition which increases your tendency to bleeding?
- Do you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- Do you suffer from swelling and irritation inside the nose?
- Do you suffer from liver or kidney disease?
- Do you suffer from heart disease?
Medicines such as Brufen Retard may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. 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 or pharmacist before taking Brufen Retard 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).
 - have any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Do you have chicken pox or shingles?
- Are you or your child dehydrated? As there is a risk of kidney damage in dehydrated children adolescents and the elderly.
- If you have an infection – please see heading "Infections" below

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 Retard and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

Infections

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

If you are taking Brufen Retard for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Can you take Brufen with other medicines? Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen 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:

- diuretics (water tablets)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Alcohol: Brufen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Brufen might make these side effects worse.

Pregnancy and breast-feeding: The use of Brufen whilst pregnant or breast feeding should be avoided. Brufen should not be used in late (the last three 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.

Driving and Using Machines: Brufen may make you feel dizzy or drowsy. If it affects you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW SHOULD YOU TAKE BRUFEN RETARD?



ALWAYS take Brufen exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist.

TAKE YOUR BRUFEN RETARD TABLETS with a glass of water. You should swallow the tablets whole without chewing, breaking, crushing or sucking on them to help prevent feeling discomfort in the mouth or irritation in the throat. The tablets are best taken in the early evening, well before retiring to bed. Take your Brufen Retard with or after food.

Your dosage will depend on what you are being treated for, the usual dose is two tablets taken as a single dose each day, preferably in the evening. In severe or acute conditions, your doctor may prescribe one extra tablet to be taken each morning in addition to the usual dose.

Brufen Retard is **NOT** suitable for children under 12 years of age.

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).

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, **tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine.** This risk may be increased if you are dehydrated.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Brufen. Tell your doctor if you have been having headaches while taking this medicine.

If you take more Brufen Retard than you should

If you have taken more Brufen Retard 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 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, cold body feeling, and breathing problems have been reported.

IF YOU FORGET TO TAKE YOUR BRUFEN RETARD TABLETS

take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS OF BRUFEN RETARD

As with all medicines, Brufen Retard may cause side effects, although they are usually mild and not everyone will suffer from 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 Brufen Retard for the shortest amount of time necessary to control your symptoms.

STOP TAKING Brufen Retard and seek immediate medical help if you experience :

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.
- Signs of intestinal bleeding such as
 - Passing blood in your faeces (stools/motions)
 - Passing black tarry stools
 - Vomiting any blood or dark particles that look like coffee grounds
 - Liver, kidney problems or difficulty urinating

Brufen Retard, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- 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].
- 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).

TELL YOUR DOCTOR AND STOP TAKING BRUFEN RETARD IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.
- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).
- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).

Medicines such as Brufen Retard have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Brufen Retard have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders such as reduction in blood cells and platelet counts – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin. Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure. Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Brufen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (affects up to 1 in 10 people):

- feeling dizzy or tired
- diarrhoea, 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 (affects up to 1 in a 100 people):

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- skin becomes sensitive to light
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)
- mouth ulcers

Rare (affects up to 1 in a 1000 people):

- feeling depressed or confused

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

- inflammation of the pancreas

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

- 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 Retard 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW SHOULD YOU STORE BRUFEN RETARD?

- Keep out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do **NOT** use after the expiry date printed on the carton label and the blister label.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION ABOUT BRUFEN RETARD

What Brufen Retard contains

- The active substance in Brufen Retard is Ibuprofen. Each Tablet contains 800mg Ibuprofen in a sustained-release formulation.
- Brufen Retard inactive ingredients: colloidal anhydrous silica, Xanthan gum, povidone, hypromellose, stearic acid, talc and titanium dioxide (E171).

What Brufen Retard looks like and contents of the pack

- White capsule shaped film-coated tablet plain on the both sides.
- Brufen Retard Tablets are available in the pack of 30 and 60 Tablets

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd., Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by

- Famar SA, 7 Anthousa Av., 153 44 Anthousa Attiki, Athens, Greece.

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