

Patient Information Leaflet

Brufen® Retard 800 mg Prolonged Release Tablets (ibuprofen)

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
- The name of this medicine is Brufen® Retard 800 mg Prolonged Release Tablets but will be referred to as Brufen Retard throughout the remainder of this leaflet
- 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

Leaflet Contents

- 1) What is Brufen Retard & what is it used for?
- 2) What should you know before taking Brufen Retard?
- 3) How should you take Brufen Retard?
- 4) Possible side effects of Brufen Retard.
- 5) How should you store Brufen Retard?
- 6) Further information about Brufen Retard.

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?
- Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

Can you take Brufen Retard with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetysalicylic acid, warfarin, ticlopidine), 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).

Pregnancy and breast-feeding:

The use of Brufen Retard whilst pregnant or breast-feeding should be avoided. Brufen Retard should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines:

Brufen Retard 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 Retard 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.

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.

IF YOU TAKE MORE BRUFEN RETARD THAN PRESCRIBED (AN OVERDOSE) you should contact a doctor or go to the nearest hospital casualty department **IMMEDIATELY** taking your tablets with you.

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

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).
- Yellowing of the eyes and/or skin (jaundice).
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis).
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems).
- Severe spreading skin rash (Stevens-Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).

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

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

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen.

Very rarely Brufen Retard may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Brufen Retard 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):

- rash
- feeling dizzy or tired
- stomach pain, indigestion, 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.
- passing black tarry stools
- passing blood in your faeces (stools/motions)
- vomiting any blood

Uncommon (affects up to 1 in a 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
- 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
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- mouth ulcers
- serious allergic reaction which causes swelling of the face or throat

Rare (affects up to 1 in a 1000 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)
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe sore throat with high fever (agranulocytosis)

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

- liver failure
- heart failure
- heart attack
- 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'
- high blood pressure

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

- worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon)

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

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

5) HOW SHOULD YOU STORE BRUFEN RETARD?

- Your tablets should be stored at room temperature (do not store above 25°C).
- They should be kept in a safe place out of the sight and reach of children, your medicine could harm them.
- Store in the original packaging in order to protect from moisture.
- Do not use this medicine after its expiry date. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return them to your pharmacist.
- If your doctor decides to stop your treatment, return any leftover tablets to your pharmacist. Only keep them if your doctor tells you to.
- 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

Each tablet contains the active ingredient ibuprofen 800 mg in a prolonged release formulation.

The other ingredients are: colloidal anhydrous silica, povidone, stearic acid, xanthan gum, hypromellose, talc, opaspray white M-1-7111B (containing: hypromellose, titanium dioxide)

What Brufen Retard looks like and contents of the pack

Brufen Retard are white pillow-shaped, film-coated, prolonged release tablets. They come in PVC/PVDC/aluminium blister strips in a printed carton.

Each pack contains 60 tablets.

Manufactured by

FAMAR S.A., 7 Anthousas Ave, 153 44 Anthousa Attiki, Greece
AbbVie Deutschland GmbH & Co. KG, Knollstrasse 50, 67061 Ludwigshafen, Germany

Procured from within the EU by the Product Licence Holder:
MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

Repackaged by XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

PL: 33532/0412

POM

Leaflet dated 23rd December 2016
Leaflet coded XXXXXXXXXX

Brufen® is a registered trademark of XXXXXXXXXXXXXXXXXXXXXXXX.

To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.