

PACKAGE LEAFLET: INFORMATION FOR THE USER

BRUFEN® RETARD

800mg Prolonged Release Tablets

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?

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1. WHAT IS BRUFEN RETARD AND 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, tendonitis, 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 800mg of ibuprofen 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?

Do not take Brufen Retard Tablets if;

- you are sensitive (allergic) to any of the ingredients in the tablets. These are listed in Section 6
- you previously experienced stomach bleeding or perforation after taking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs)

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

Take special care with Brufen Retard Tablets if:

- you have, or previously suffered from bronchial asthma, chronic rhinitis or allergic diseases
- you suffer from liver, kidney or heart disease
- you suffer from high blood pressure (hypertension)
- you are elderly - elderly people are more prone to side effects to NSAIDs, particularly stomach bleeding and perforation which can be fatal
- you have, or you previously had a stomach ulcer, stomach bleeding or other gastric complaint
- you are dehydrated
- you have a condition which increases your tendency to bleeding or have bleeding in the skull – please see above
- you have lupus or a connective tissue disease (autoimmune diseases affecting connective tissue)

If any of these apply to you, please tell your doctor or pharmacist BEFORE taking any Brufen Retard Tablets.

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.

Anti-inflammatory/pain-killer medicines like Brufen Retard 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 or pharmacist before taking Brufen Tablets 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

Taking other Medicines

Can you take Brufen Retard with other medicines?

Brufen Retard 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, 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 Retard. You should therefore always seek the advice of your doctor or pharmacist before you use Brufen Retard 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
- any oral medicines used to treat diabetes (e.g. metformin, or any sulphonylurea medicines)
- a herbal remedy called ginkgo biloba (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)

Pregnancy and breast-feeding:

Please tell your doctor if you are, or think you are, pregnant. Brufen Retard is not recommended during the first and second trimesters (first 6 months) of pregnancy unless clearly necessary and should not be taken during the third trimester (last 3 months) of pregnancy. Brufen Retard is not recommended while breast feeding.

Driving and Using Machines:

Medicines such as Brufen Retard may cause dizziness, drowsiness, tiredness and problems with vision. If affected, you should not drive or operate machine

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 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.

DOSAGE:

Adults - 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.

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

take them 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 tablets for the shortest amount of time necessary to control your symptoms.

If you suffer from any of the following at any time during your treatment STOP TAKING Brufen Retard and seek immediate medical help:

- Severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING THE TABLETS IF YOU EXPERIENCE:

- Hypersensitivity reactions such as unexplained wheezing, shortness of breath, skin rash, itching or bruising
- Unexplained stomach pain or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting
- Yellowing of the eyes and/or skin
- Severe sore throat with high fever (these may be the symptoms of a condition known as agranulocytosis)
- Blurred or disturbed vision or seeing/hearing strange things
- Fluid retention (e.g. swollen ankles)

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

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

Brufen Retard may hide the signs of an underlying infection.

Other side effects of Brufen Retard may include:

- nausea, vomiting, diarrhoea, flatulence (wind), constipation, stomach ache
- mouth ulcer
- duodenal ulcer
- stomach perforation
- increase in severity of Crohn's disease or colitis
- inflammation of the stomach lining
- inflammation of the pancreas
- high blood pressure (hypertension)
- heart failure
- nasal stuffiness or runny nose (rhinitis)
- blood disorders such as a reduction in different types of cells in the blood
- difficulty sleeping, anxiety, depression, confusion
- headaches, numbness or tingling, dizziness, drowsiness, tiredness, generally feeling unwell
- blurred or disturbed vision, inflammation of optic nerve
- balance disorder which makes you feel unsteady, giddy, woozy, or have a sensation of movement, spinning, or floating (vertigo), ringing in the ears, hearing problems
- liver problems such as hepatitis or jaundice
- skin problems such as increased sensitivity to light and severe reactions (such as blistering of the skin, mouth, eyes and genitals)
- kidney problems, including reduced kidney function and kidney failure

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

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 not be stored above 25°C. They should be kept in a safe place out of the reach and sight of children, your medicine could harm them.

The tablets should be kept in their original packaging in order to protect from moisture. Do NOT take Brufen Retard Tablets after the 'expiry' date shown on the carton and blister.

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.

6. FURTHER INFORMATION ABOUT BRUFEN RETARD

The active substance in Brufen Retard 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 tablets are white, pillow-shaped and film-coated. The tablets are available in blister packs, each containing 60 tablets.

Brufen Retard inactive ingredients: xanthan gum, povidone, hypromellose, stearic acid, colloidal anhydrous silica, talc, Opaspray white M-1-7111B (containing hypromellose and titanium dioxide (E171)).

Marketing Authorisation Holder:

BGP Products Ireland Limited
4051 Kingswood Drive
Citywest Business Campus
Dublin 24
Ireland.

Manufacturer:

FAMAR S.A.
7 Anthousas Ave
153 44 Anthousa Attiki
Greece.

And:

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

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