



### 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.

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 National reporting systems listed below:

##### UK:

The Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

##### MALTA:

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

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 normal room temperature (below 25 °C) in a safe place out of the reach and sight of children as your medicine could harm them. They should be kept in their original packaging. Do **NOT** take Brufen Retard after the 'use by' date shown on the carton. 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, in a sustained release (slow-release) formulation. The tablets are available in calendar packs, each containing 56 tablets

**Brufen Retard ingredients:** Each tablet contains 800mg of Ibuprofen PhEur, xanthan gum, povidone, hypromellose, stearic acid, colloidal anhydrous silica, talc and Opaspray White M-1-7111B (containing hypromellose and titanium dioxide).

**Marketing Authorisation Holder:**  
Mylan Products Ltd.  
20 Station Close, Potters Bar, Herts, EN6 1TL, UK  
**Manufacturer:**  
FAMAR A.V.E. Anthoussa Plant,  
Anthoussa Avenue 7, Anthoussa Attiki, 153 49 Greece  
Leaflet was last revised in February 2024

  
ART-182-04  
31055009

VIATRIS				Date: 31 JAN 2024	Time: 12:10		
Description	Brufen Retard, 800 mg, 56			No. of colours	1	Page Count	2 of 2
Component Type	Leaflet/IFU - Folded	Site Barcode/DataMatrix	980 = 111010101	Colours			
Affiliate Item Code	ART-182-04	Viatrix SAP No.	400542145	Non-Print Colours			
Superseded Affiliate Item Code	ART-182-03	Vendor Job No.	N.A.	Equate CMYK with			
TrackWise/GLAMS Job No.	ART-182-04	Artwork Proof No.	4	Main Font	Helvetica Neue	Body Text Size	8 pt
MA No.	PL 46302/0010	Client Market	United Kingdom	Dimensions	148 x 420 mm, folded at 148 x 210mm	Min Text Size used	8 pt
Supplier SAP No.	N.A.	Barcode Info	N.A.	Packing Site/Printer	Famar Greece (Anthoussa - GR)		
New Supplier Code	31055009	3D Render ID	N.A.	Keyline/Drawing No.	CP600-MB451-MB440		
Superseded Supplier Code	31053564			Sign-offs			
V3 MAY 2023							