

- Sunset yellow dye (E110) may cause allergic reactions, Methyl para-hydroxybenzoate (E218) and propyl para-hydroxybenzoate (216) may cause allergic reactions (possibly delayed).
- This medicine contains 0.5mg Sodium Benzoate in each 5ml dose.

This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially ‘sodium-free’.

3. How should you take Brufen Syrup?

ALWAYS take Brufen Syrup 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. Ensure the bottle is thoroughly shaken before use. Take with or after food.

DOSAGE:

Adults and children over 12 years -The usual dosage is 4 to 6 spoonfuls (5 ml) taken three times a day. Your doctor may choose to increase or decrease this depending on what you are being treated for; but no more than 24 spoonfuls (120 ml/2400 mg) should be taken in one day.

Children - Brufen Syrup should **NOT** be taken by children weighing less than 7 kg. When used to treat fever, the syrup should not be used long term or given to children under the age of 1 year.

The usual dose in children is 20 mg per kg of bodyweight each day, in divided doses. This can be given as follows:
1-2 years: One 2.5 ml (50 mg) dose three/four times a day
3-7 years: One 5 ml (100 mg) dose three/four times a day
8-12 years: Two 5 ml (200 mg) doses three/four times a day
The doctor may choose to increase this dose in children with juvenile rheumatoid arthritis. This dose should not exceed 40mg/kg bodyweight daily in divided doses.

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.

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).

If you take more Brufen Syrup than you should

If you have taken more Brufen Syrup 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 SYRUP 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 Syrup

As with all medicines, Brufen Syrup 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 syrup for the shortest amount of time necessary to control your symptoms.

STOP TAKING Brufen Syrup 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 Syrup, 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 SYRUP 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 Syrup have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Brufen Syrup 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 Syrup 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:

UK:

The Yellow Card Scheme at: 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

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

5. How should you store Brufen Syrup?

Your Brufen Syrup should be stored at normal room temperature (below 25°C) and protected from direct light. It should be kept in a safe place out of the reach and sight of children as your medicine could harm them.

It should be kept in its original packaging. Do **NOT** take Brufen Syrup after the ‘expiry’ date shown on the bottle. Once the bottle is opened, the Brufen Syrup must be used within 12 months.

If your doctor decides to stop your treatment, return any left over product to your pharmacist. Only keep it if your doctor tells you to.

6. Further information about Brufen Syrup

The active substance in Brufen Syrup is Ibuprofen BP. Each bottle contains 500 ml of syrup.

Brufen Syrup inactive ingredients: purified water, sucrose, glycerine, sorbitol, agar, citric acid monohydrate, sodium benzoate (E221), methyl hydroxybenzoate (E218), polysorbate 80, propyl hydroxybenzoate (E216), orange flavour, sunset yellow (E110).

<p>Marketing Authorisation Holder: Mylan Products Ltd. 20 Station Close, Potters Bar, Herts, EN6 1TL, UK</p> <p>Manufacturer: AbbVie S.r.l., S.R. 148 Pontina km 52 snc, 04011 campoverde di Aprilia (LT), Italy.</p> <p>Leaflet last revised in January 2024.</p>
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BACK

Description			Date: 18 JAN 2024		Time: 10:30	
Description	Brufen, 100 mg/5 ml, 500 ml		No. of colours	1	Page Count	2 of 2
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Superseded Affiliate Item Code	ART-186-05	Vendor Job No.	N.A.	Non-Print Colours	Keyline	
TrackWise/GLAMS Job No.	ART-186-06	Artwork Proof No.	1			
MA No.	PL 46302/0011	Client Market	United Kingdom	Equate CMYK with		
Supplier SAP No.	N.A.	Barcode Info	N.A.			
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Superseded Supplier Code	20077322			Dimensions	flat: 150x530mm; folded: 150x28mm with 2mm step	Min Text Size used 9 pt
Packing Site/Printer	AbbVie (Campoverde - IT)		Keyline/Drawing No.	flat: 150x530mm; folded: 150x28mm with 2mm step		
Sign-offs						
						V3 MAY 2023