

pharmacode reading direction

20083518

Brufen[®] Syrup Ibuprofen 100 mg/5ml

IMPORTANT INFORMATION

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

- Keep this leaflet as you may need to read it
- This leaflet provides a summary of the information currently available about Brufen Syrup
- 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 Syrup & what is it used for?
- 2. What should you know before taking Brufen Syrup?
- 3. How should you take Brufen Syrup?
- 4. Possible side effects of Brufen Syrup.
- 5. How should you store Brufen Syrup?

6. Further information about Brufen Syrup.

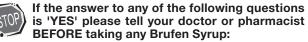
1. What is Brufen Syrup & what is it used for?

Brufen Syrup belongs to a group of medicines called antiinflammatory 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 Syrup can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine. It can also be used for the short term treatment of fever in children over the age of 1 year.

The active ingredient in Brufen Syrup is ibuprofen. Each 5ml spoonful of Brufen Syrup contains 100mg ibuprofen.

2. What should you know before taking Brufen Syrup?



- Are you pregnant or planning to become pregnant, or are you breast-feeding? Brufen Syrup 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 syrup? These are listed in Section 6. Some people may be sensitive to the E110, methyl hydroxybenzoate, propyl hydroxybenzoate or sodium benzoate and if you develop an unexpected rash, sore eyes, sore mouth or difficulty breathing whilst taking the medicine stop taking it and contact your doctor for advice.
- Do you have, or have you previously had, a stomach ulcer or other gastric complaint? Do not take Brufen Syrup 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 erythema multiforme. Stevens-Johnson syndrome, toxic always seek the advice of your doctor or pharmacist before months of) pregnancy as it could harm your unborn child or to bleedina?
- 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 Syrup 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 Syrup 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?
- · Have you been told by your doctor that you have an intolerance to some sugars? Due to the content of sorbitol or 26.4g per dose) it is not recommended for those with hereditary fructose intolerance, glucose malabsorption syndrome or sucraseisomaltase deficiency.
- 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'

Skin reactions

Serious skin reactions including exfoliative dermatitis,

epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in of the following medicines in addition to those mentioned association with ibuprofen treatment. Stop using Brufen Syrup and seek medical attention immediately if you notice • diuretics (water tablets) any of the symptoms related to these serious skin reactions • cardiac glycosides, such as digoxin, used to treat heart 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 Syrup and contact immediately your doctor or medical emergencies if you notice any of these signs.

Infections

FRONT

Brufen may hide signs of infections such as fever and pain. It is therefore possible that Brufen 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 Syrup 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/ (70 mg per ml or 2.8 g per dose) and sucrose (660 mg per ml 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?

Alcohol: Brufen may cause some side effects including Some medicines that are anti-coagulants (i.e. thin blood/ dizziness, drowsiness and stomach problems such as prevent clotting e.g. aspirin/acetylsalicyclic acid, warfarin, bleeding in the stomach. Drinking excessive alcohol while ticlodipine), some medicines that reduce high blood taking Brufen might make these side effects worse. pressure (ACE-inhibitors such as captopril, beta-blockers Pregnancy and breast-feeding: The use of Brufen Syrup such as atenolol, or angiotensin-II receptor antagonists whilst pregnant or breast feeding should be avoided. such as losartan) and other medicines may affect or be Brufen Syrup should not be used in late (the last three affected by treatment with ibuprofen. You should therefore

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Sign-offs						

should tell your doctor or pharmacist if you are taking any above

- 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 guinolones 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 sulphonvlureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- gingko biloba herbal medicine (there is a chance you may
- bleed more easily if you are taking this with ibuprofen).

you use ibuprofen with other medicines. In particular you 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 Syrup 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.

Brufen Syrup contains sucrose, sorbitol, sunset yellow (E110), sodium benzoate (E221),

methyl para-hydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)

- Brufen contains 3 g sucrose per 5 ml dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This should be taken into account in patients with diabetes mellitus and may be harmful to teeth.
- This medicine contains 500 mg sorbitol in each 5 ml dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

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- Sunset yellow dye (E110) may cause allergic reactions. Methyl para-hydroxybenzoate (E218) and propyl parahydroxybenzoate (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 Svrup 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 If you take more Brufen Syrup than you should 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 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 Svrup 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 briaht 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 arounds
- Liver, kidney problems or difficulty urinating

Brufen Syrup, especially when taken at higher than recommended doses or for a prolonged period of time, can been associated with severe skin problems for patients 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 **Uncommon (affects up to 1 in a 100 people):** 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, sneezing, blocked, itchy or runny nose (rhinitis) itching or bruising (these may be symptoms of an stomach or gut ulcer, hole in the wall of the digestive tract allergic reaction). inflammation of your stomach lining
- Loss of vision, blurred or disturbed vision (visual impairment) • ringing in ears (tinnitus) or seeing/hearing strange things (hallucinations). sensation of spinning (vertigo)

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 with chicken pox or shingles

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.

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- Blood disorders such as reduction in blood cells and

- feeling drowsv
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- skin becomes sensitive to light
- hearing problems
- 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).

Marketing Authorisation Holder: Mylan Products Ltd. 20 Station Close, Potters Bar, Herts, EN6 1TL, UK

Manufacturer: AbbVie S.r.I., S.R. 148 Pontina km 52 snc. 04011 campoverde di Aprilia (LT). Italy.

Leaflet last revised in January 2024.

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