

PACKAGE LEAFLET: INFORMATION FOR THE USER

BRUFEN

600mg Granules

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?

1. What are Brufen Granules & what are they used for?
2. What should you know before taking Brufen Granules?
3. How should you take Brufen Granules?
4. Possible side effects of Brufen Granules.
5. How should you store Brufen Granules?
6. Further information about Brufen Granules.

1. WHAT ARE BRUFEN GRANULES & WHAT ARE THEY USED FOR?

Brufen Granules belong to a group of medicines called antiinflammatory pain killers.

They 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 Granules 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 Granules is ibuprofen and each sachet contains 600 mg.

2. WHAT SHOULD YOU KNOW BEFORE TAKING BRUFEN GRANULES?

If the answer to any of the following questions is 'YES' please tell your doctor or pharmacist BEFORE taking any Brufen

Granules:

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Brufen Granules 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 granules? 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 Granules 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 liver or kidney disease?
- Do you suffer from heart disease?

Medicines such as Brufen Granules 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. If you have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes, high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

- Do you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- Has your doctor advised you to follow a low sodium diet?
- Have you been told by your doctor that you have an intolerance to some sugars?
- Is your child dehydrated? As there is a risk of kidney damage in dehydrated children and adolescents.

Can you take Brufen with other medicines?

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine), 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)
- 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 preparations, 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 (types of anti-fungal drugs)
- Gingko 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 Granules whilst pregnant or breast feeding should be avoided. Brufen Granules 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 Granules may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW SHOULD YOU TAKE BRUFEN GRANULES?

ALWAYS take Brufen Granules 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 GRANULES by emptying the contents of the sachet into a glass full of water to make an orange flavoured fizzy drink, stir and drink immediately.

Take with or after food.

DOSAGE:

Adults and Children over 12 years - The usual dosage is 1 sachet taken two or 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 4 sachets should be taken in one day.

Brufen Granules are NOT recommended for children under 12 years of age.

IF YOU TAKE MORE BRUFEN GRANULES THAN PRESCRIBED (AN OVERDOSE)

you should contact a doctor or go to the nearest hospital casualty department IMMEDIATELY taking your granules with you.

IF YOU FORGET TO TAKE YOUR BRUFEN GRANULES

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 GRANULES

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

STOP TAKING Brufen Granules 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 THE GRANULES 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).

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

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen. Very rarely Brufen Granules may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

Other side effects may include headache, hallucinations, dizziness, tingling of hands and feet, ringing in the ears, depression, confusion, difficulty sleeping, anxiety, impaired hearing, a temporary sensation of burning in the mouth or throat, diarrhoea, constipation, flatulence (wind), unexpected sensitivity of the skin to the sun, tiredness, malaise, mood swings and swelling and irritation inside the nose.

Brufen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

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 GRANULES?

- Keep out of the sight and reach of children.
- Do not use Brufen Granules after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If the granules become discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- If your doctor decides to stop your treatment, return any left over product 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 GRANULES

The active substance in Brufen Granules is ibuprofen. Each sachet contains 600mg of ibuprofen in effervescent granule form.

Brufen Granules inactive ingredients: microcrystalline cellulose, croscarmellose sodium, malic acid, sodium saccharin, sucrose, povidone, sodium bicarbonate, sodium carbonate anhydrous, orange flavour and sodium lauryl sulphate.

Brufen Granules are white, effervescent, orange flavoured granules provided in single dose sachets. Each pack contains 20 sachets.

Manufacturer and Product Licence holder

Brufen Granules are manufactured by:

AbbVie S.r.L. S.R. 148 Pontina km 52 snc, 04011 Campoverde di Aprilia (LT), Italy.

Procured from within the EU and repackaged by the Product Licence holder: G-Pharma Ltd., Dakota Avenue, Salford M50 2PU.

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