

BRUFEN® TABLETS

Ibuprofen

200, 400 & 600 mg



IMPORTANT INFORMATION

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

- Keep this leaflet as you may need to read it again
- This leaflet provides a summary of the information currently available about Brufen Tablets
- 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

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1. What are Brufen Tablets & what are they used for?

Brufen Tablets belong to a group of medicines called anti-inflammatory 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 Tablets 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 Tablets is ibuprofen and each tablet contains either 200, 400 or 600 mg.

2. What should you know before taking Brufen Tablets?



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

- Are you pregnant or planning to become pregnant, or are you breast-feeding? Brufen Tablets 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 tablets? 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 Tablets 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 Tablets 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)?
- Have you been told by your doctor that you have an intolerance to some sugars?
- 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 whilst pregnant or breast feeding should be avoided.

Brufen 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 may make you feel dizzy or drowsy. If the tablets 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 Tablets?



ALWAYS take Brufen Tablets 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 Tablets with or after food, with a glass of water. Brufen Tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat.

DOSAGE:

Adults - The usual dosage is 600 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for, but no more than 2400 mg should be taken in one day.

Children - The usual daily dosage is 20 mg per kg of bodyweight, given in divided doses. Brufen Tablets should **NOT** be taken by children weighing less than 7 kg.

In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg in divided doses.

IF YOU TAKE MORE BRUFEN TABLETS 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 TABLET

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 Tablets

As with all medicines, Brufen Tablets 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 Tablets and seek *immediate medical help*:

- Severe headache, high temperature, stiffness of the neck or intolerance to 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:

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

Medicines such as Brufen Tablets 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 Tablets 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, 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.

5. How should you store Brufen Tablets?

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.

They should be kept in their original packaging, do NOT take Brufen Tablets after the 'use by' date shown on the carton.

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

6. Further information about Brufen Tablets.

The active substance in Brufen Tablets is Ibuprofen Ph.Eur. available as either 200, 400 or 600 mg tablets. The tablets are white, pillow-shaped and film-coated.

They are supplied in blister packs containing either 60 or 100 tablets.

Brufen Tablets inactive ingredients: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, colloidal anhydrous silica, sodium laurilsulfate, magnesium stearate, Opaspray white M-1-7111B (comprising hypromellose 2910 and titanium dioxide), dry colour dispersion, white 06A28611 (or a combination of Opaspray white M-1-7111B, hypromellose and talc).

Marketing Authorisation Holder:

Abbott Laboratories Ltd.,
Abbott House, Vanwall Business Park,
Vanwall Road, Maidenhead, Berkshire, SL6 4XE, UK.

Manufacturer:

FAMAR S.A., 7 Anthousas Av.,
153 44 Anthousa Attiki, Greece.
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