

## **BRUFEN®TABLETS**

**Ibuprofen**

**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 belongs 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 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 swelling and irritation inside the nose?
- 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. You should discuss your treatment with your doctor or pharmacist before taking Brufen Tablets 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?
- 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 have been reported in association with Brufen Tablets treatment. You should stop taking Brufen Tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

#### Infections

Brufen tablets may hide signs of infections such as fever and pain. It is therefore possible that Brufen tablets 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.

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

**Alcohol:** Brufen may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Brufen might make these side effects worse.

**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.

**Brufen contains lactose monohydrate**

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 medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.**

### **3. How should you take Brufen Tablets?**

**ALWAYS** take Brufen 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 and children over 12 years** - 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 dose is 20 mg per kg of bodyweight each day, given in divided doses. Brufen Tablets should **NOT** be taken by children weighing less than 7 kg. The 600 mg tablets should not be given to children under the age of 12 years.

In cases of severe juvenile arthritis your doctor may increase the dosage up to 40 mg/kg 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 than you should**

If you have taken more Brufen 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 TABLETS** 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.

#### **STOP TAKING Brufen Tablets 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 BRUFEN TABLETS 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).
- Severe spreading skin rash ('Stevens-Johnson Syndrome', 'toxic epidermal necrolysis' and 'erythema multiforme', symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

Medicines such as Brufen Tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Brufen Tablets 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 Tablets 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 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 as 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 leftover 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 a 400 or 600 mg tablet. The tablets are white, pillow shaped and film-coated.

They are supplied in blister packs containing 60 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).

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