

Consumer Medicine Information**PLEASE READ THIS INFORMATION CAREFULLY****What is in this leaflet**

This leaflet answers some common questions about BRUFEN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BRUFEN against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BRUFEN is used for

BRUFEN relieves pain and reduces inflammation (swelling, redness or soreness) that may occur:

- in different types of arthritis including rheumatoid arthritis, osteoarthritis and juvenile rheumatoid arthritis
- in muscle and bone injuries such as sprains, strains, lower back pain (lumbago), rheumatism, and tendonitis, such as tennis elbow
- from swelling and pain after setting broken or dislocated bones
- menstrual cramps (period pain)
- following surgery
- due to dental pain

BRUFEN also relieves fever (high temperature).

Although BRUFEN can relieve the symptoms of pain and inflammation, it will not cure your condition.

BRUFEN belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs).

Ask your doctor if you have any questions about why BRUFEN has been prescribed for you.

Your doctor may have prescribed BRUFEN for another reason.

This medicine is available only with a doctor's prescription.

BRUFEN is not addictive.

Before you take BRUFEN**When you must not take it**

Do not take BRUFEN if you have an allergy to:

- any product containing ibuprofen
- any of the ingredients listed at the end of this leaflet
- aspirin or any other NSAID medicine

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- hives, itching or skin rash
- stomach ache, fever, chills, nausea and vomiting.
- fainting

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or

NSAID medicines. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

If you are allergic to aspirin or any other NSAID medicines and take BRUFEN, these symptoms may be severe.

Do not take BRUFEN if:

1. **you are pregnant or intend to become pregnant.**
BRUFEN may affect your developing baby if you take it during pregnancy.
2. **you are breast-feeding or intend to breast-feed.**
BRUFEN passes into breast milk and may affect your baby.
3. **you have (or have previously) vomited blood or material that looks like coffee grounds.**
4. **you are (or have previously) bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.**
5. **you have a condition resulting in an increased tendency to bleed.**
6. **you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.**
7. **you have, or have a history of, Ulcerative Colitis or Crohn's Disease**
8. **you have severe heart failure**
9. **you have severe liver disease**
10. **you have severe kidney disease**

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you have any allergies to:**
 - any other substances, such as medicines, foods, preservatives or dyes
2. **you are pregnant or intend to become pregnant.**
Like most NSAID medicines, BRUFEN is not recommended to be used during pregnancy. It may also impair female fertility.
3. **you are breast-feeding or plan to breast-feed.**
Like most NSAID medicines, BRUFEN is not recommended while you are breast-feeding.
4. **you have or have had any medical conditions, especially the following:**
 - heart disease or high blood pressure
 - heartburn, indigestion, stomach ulcer or any other stomach problems
 - vomiting blood or bleeding from the back passage
 - severe skin reactions such as Stevens-Johnson syndrome
 - asthma
 - vision problems
 - liver or kidney disease

- tendency to bleed or other blood problems
- bowel or intestinal problems such as ulcerative colitis or Crohn's Disease
- heart failure
- swelling of the ankles or feet
- diarrhoea

5. you currently have an infection

If you take BRUFEN while you have an infection, it may hide some of the signs and symptoms of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

6. you plan to have surgery

If you have not told your doctor about any of the above, tell them before you start taking BRUFEN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BRUFEN may interfere with each other. These include:

- aspirin, salicylates or other NSAID medicines
- warfarin, medicines used to stop blood clots
- lithium, a medicine used to treat some types of depression
- SSRIs such as sertraline, medicines used to treat depression
- various medicines used to treat high blood pressure or other heart conditions
- medicines used to treat heart failure such as digoxin
- diuretics, also called fluid tablets
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- ciclosporin or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection
- aminoglycosides, medicines used to treat certain infections
- Gingko biloba, an herbal medicine used to thin the blood
- quinolone antibiotics, medicines used to treat certain infections
- zidovudine, a medicine used to treat HIV
- colestyramine, a medicine used to treat high cholesterol
- sulfonylureas, medicines to treat diabetes
- voriconazole or fluconazole, medicines to treat certain fungal infections
- mifepristone (RU-486), a medicine used to end a pregnancy

These medicines may be affected by BRUFEN or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take BRUFEN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many BRUFEN tablets to take each day and when to take them.

Take the exact amount your doctor tells you to, no more or less.

Adults and Children Over 12 Years of Age

The usual daily dose of BRUFEN is one tablet taken three or four times a day.

In acute conditions, your doctor may prescribe two tablets three times a day.

Do not take more than six tablets in one day.

It is usual for elderly patients to be prescribed a smaller dose of BRUFEN.

Period Pain

The usual dose of BRUFEN is one to two tablets at the first sign of pain or menstrual bleeding.

Then take one tablet every 4 to 6 hours as necessary.

Do not take more than four tablets in one day.

How to take it

Take BRUFEN with or straight after food with a full glass of water.

This may help reduce the possibility of an upset stomach.

How long to take it

Do not take BRUFEN for longer than your doctor tells you to.

Depending on your condition, you may need BRUFEN for a few days, a few weeks or for longer periods.

As with other NSAID medicines, if you are taking BRUFEN for arthritis, it will not cure your condition, but it should help to control pain, swelling and stiffness.

BRUFEN usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine.

If you have arthritis, BRUFEN should be taken every day for as long as your doctor prescribes.

For period pain, BRUFEN should be taken for a few days until the pain goes away.

If you are not sure how long to take BRUFEN for, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much BRUFEN. Do this

even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much BRUFEN you may experience the following:

- feel sick or vomit
- have stomach pain
- have convulsions
- feel tired, drowsy or lack energy
- feel dizzy or even become unconscious
- have a headache or ringing in the ears
- unusual eye movements, shivering, confusion, interrupted or breathing difficulties
- low blood pressure, low or rapid heart beat

While you are using BRUFEN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BRUFEN.

Tell any other doctors, dentists and pharmacists that are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

NSAID medicines can slow down blood clotting.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you get an infection while taking this medicine, tell your doctor.

BRUFEN may hide some of the signs of an infection and may make you think mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if you get any visual disturbances such as blurred vision.

You may need to have an eye examination to make sure BRUFEN is not causing any side effects.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the medicine is not helping your condition.

This will help your doctor to determine the best treatment for you.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not take any other medicines to relieve pain and reduce inflammation while you are taking BRUFEN without first telling your doctor.

This includes:

- aspirin (also called acetylsalicylic acid)
- other medicines containing ibuprofen, the active ingredient in BRUFEN
- any other NSAID medicine

Do not take BRUFEN to treat any other complaints unless your doctor tells you to.

Do not give BRUFEN to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of:

Be careful driving or operating machinery until you know how BRUFEN affects you.

As with other NSAID medicines, BRUFEN may cause dizziness or light-headedness, drowsiness or blurred vision in some people.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BRUFEN.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea or vomiting
- loss of appetite
- heartburn or pain in the upper part of your stomach
- cramps, wind, constipation or diarrhoea
- headache
- sleepiness
- dizziness
- buzzing or ringing in the ears or other trouble hearing
- sleeplessness
- changes in mood, for example feeling anxious, depression, confusion, nervousness

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- yellowing of the skin and/or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- tingling of the hands and feet
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations

These may be serious side effects of BRUFEN. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking BRUFEN and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck
- hearing difficulties, ringing in the ears

BRUFEN may be associated with a small increased risk of heart attack (myocardial infarction).

Blood disorders and kidney problems may occur with BRUFEN.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

After using BRUFEN

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep the tablets in a cool dry place where the temperature stays below 25°C.

Do not store BRUFEN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What BRUFEN looks like

BRUFEN tablets are white, pillow shaped film-coated tablets.

The tablets are available in a blister pack containing 30 tablets.

Ingredients

BRUFEN contains 400 mg of ibuprofen as the active ingredient.

The inactive ingredients are:

- microcrystalline cellulose
- croscarmellose sodium
- lactose monohydrate
- colloidal anhydrous silica
- sodium lauryl sulfate
- magnesium stearate
- hypromellose
- purified talc
- titanium dioxide

BRUFEN does not contain gluten, tartrazine or any other azo dyes.

Supplier

BRUFEN is supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point, NSW 2000
www.mylan.com.au

For Medical Information Phone: 1800 314 527

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Things that would be helpful for your arthritis

Some self-help measures suggested below may help your condition.

Talk to your doctor, physiotherapist, or pharmacist about these measures and for more information.

Weight

Your doctor may suggest losing some weight to reduce the stress on your joints.

Exercise

May be recommended by your doctor or physiotherapist to help keep or improve movement and strengthen muscles.

Ask a physiotherapist for an exercise plan suited to your condition.

As a general rule if any exercise hurts then do not do it.

Rest

Is important and is usually balanced with exercise and activity. Rest is needed when joints are hot, swollen or painful.

Heat

Hot showers or baths may help to ease the pain and relax the muscles that can become tense with arthritis. Your physiotherapist or doctor can prescribe other forms of heat treatment.

Physical Aids

Are available to help with daily household tasks. For example, there are gadgets and aids to help turn on taps, remove screw tops, pick up objects and handles that can be fitted in bathrooms. Ask your doctor for more information.

This leaflet was prepared in February 2020.