BRUFEN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking BRUFEN?

BRUFEN contains the active ingredient ibuprofen. BRUFEN is used to relieve pain and reduce inflammation. For more information, see Section 1. Why am I taking BRUFEN? in the full CMI.

2. What should I know before I take BRUFEN?

Do not take if you have ever had an allergic reaction to ibuprofen or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding. For more information, see Section 2. What should I know before I take BRUFEN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BRUFEN and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take BRUFEN?

- 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, not more or less.

More instructions can be found in Section 4. How do I take BRUFEN? in the full CMI.

5. What should I know while taking BRUFEN?

Things you should do	• Tell any other doctors, dentists, surgeons, anaesthetists and pharmacists that are treating you that you are taking this medicine. • Tell your doctor immediately if you become pregnant while taking this medicine. • Tell your doctor if you get an infection while taking this medicine. • Tell your doctor if you get any visual disturbances such as blurred vision. • Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. • Tell your doctor if you feel the medicine is not helping your condition. • Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not take any other medicines to relieve pain and reduce inflammation while you are taking BRUFEN without first telling your doctor. • 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.
Driving or taking machines	• 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.
Looking after your medicine	• Keep the tablets in a cool dry place where the temperature stays below 25°C. Protect from moisture.

For more information, see Section 5. What should I know while taking BRUFEN? in the full CMI.

6. Are there any side effects?

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. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

BRUFEN®

Active ingredient(s): *ibuprofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking BRUFEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking BRUFEN.**

Where to find information in this leaflet:

1. Why am I taking BRUFEN?
2. What should I know before I take BRUFEN?
3. What if I am taking other medicines?
4. How do I take BRUFEN?
5. What should I know while taking BRUFEN?
6. Are there any side effects?
7. Product details
8. Things that would be helpful for your arthritis

1. Why am I taking BRUFEN?

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

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.

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.

BRUFEN is not addictive.

2. What should I know before I take BRUFEN?

Warnings

Do not take BRUFEN if:

- you are allergic to ibuprofen, or any of the ingredients listed at the end of this leaflet.
- you take 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

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- take any medicines for any other conditions.
- take 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.
- have any allergies to any other substances, such as medicines, foods, preservatives or dyes.
- 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.
- are breastfeeding or plan to breastfeed. Like most NSAID medicines, BRUFEN is not recommended while you are breastfeeding.
- 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
- 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.
- plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

BRUFEN may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

BRUFEN passes into breast milk and may affect your baby.

Do not take BRUFEN if:

- you have (or have previously) vomited blood or material that looks like coffee grounds.
- you are (or have previously) bleeding from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.
- you have a condition resulting in an increased tendency to bleed.
- you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.
- you have, or have a history of Ulcerative Colitis or Crohn's Disease
- you have severe heart failure
- you have severe liver disease
- you have severe kidney disease

3. What if I am taking other medicines?

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

Some medicines may interfere with BRUFEN and affect how it works.

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, a 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BRUFEN.

4. How do I take BRUFEN?

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, not 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.

Follow the instructions provided and take BRUFEN until your doctor tells you to stop.

When to take BRUFEN

- BRUFEN should be taken as directed by your doctor or pharmacist.
- 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.

How to take BRUFEN

- Take BRUFEN with or straight after food with a full glass of water.
- This may help reduce the possibility of an upset stomach.

If you forget to take BRUFEN

BRUFEN should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

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

If you take too much BRUFEN

If you think that you have taken too much BRUFEN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

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

5. What should I know while taking BRUFEN?

Things you should 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 should 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 medicines
- 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.

Driving or taking machines

Be careful before you drive or take any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

BRUFEN may cause some side effects including dizziness, headache and stomach problems. Drinking alcohol with BRUFEN might make these side effects worse.

Looking after your medicine

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

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• nausea or vomiting • loss of appetite • heartburn or pain in the upper part of your stomach • mouth ulcers • 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 • a rash that always appears in the exact same spot on your skin (fixed eruption)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Rare serious side effects	What to do
• 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	**Call your doctor straight away if you notice any of these serious side effects, you may need urgent medical attention.**
• symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal • severe or persistent headache • fast or irregular heart beats, also called palpitations	

Very rare serious side effects	What to do
• 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 • Shortness of breath, chest discomfort or palpitation which can be a sign of a potentially serious allergic reaction called Kounis syndrome • Low level of potassium in your blood • Muscle weakness and muscle pain	**Stop taking BRUFEN and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.**

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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What BRUFEN contains

Active ingredient (main ingredient)	400 mg of ibuprofen
Other ingredients (inactive ingredients)	• microcrystalline cellulose • croscarmellose sodium • lactose monohydrate • colloidal anhydrous silica • sodium lauryl sulfate • magnesium stearate • hypromellose • purified talc • titanium dioxide
Potential allergens	sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What BRUFEN looks like

BRUFEN are white, pillow-shaped film-coated tablets (AUST R 80659).

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

Who distributes BRUFEN

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

BRUFEN® is a Viatris company trade mark.

8. 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

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

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.

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