NEW ZEALAND CONSUMER MEDICINE INFORMATION

BRUFEN®
Ibuprofen film-coated tablet 200 mg

What in this leaflet
Please read this leaflet carefully before you start BRUFEN.
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.
If you have any concerns about taking 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 or redness) that occur with:
- Headache
- Migraine headache
- Tension headache
- Dental pain
- Backache
- Muscular pain
- Period pain
- Arthritic pain
- Sinus pain
- Cold and flu symptoms.

BRUFEN also relieves fever (high temperature).

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

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

This medicine is available from pharmacies without a 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 medicine 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; rash, itching or hives on the skin.

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 pharmacist.

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

Do not take BRUFEN if you have an allergy to any medicine containing ibuprofen or any of the ingredients listed at the end of this leaflet.

Do not take BRUFEN if you have an allergy to aspirin or any other NSAID medicine.

Before you start to take it
Tell your doctor or pharmacist if you have allergies to any other medicines, including aspirin or other NSAID medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

Do not take BRUFEN if you are (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea.

Do not take BRUFEN if you have a condition resulting in an increased tendency to bleed.

Do not take BRUFEN if you have a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.

Do not take BRUFEN if you have, or have a history of, ulcerative colitis or Crohn’s disease.

Do not take BRUFEN if you have severe heart failure, liver failure or kidney disease.

Do not take this medicine 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 or pharmacist.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding or plan to breast-feed.

Like most NSAID medicines, BRUFEN is not recommended while you are pregnant or breast-feeding.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:
• heart disease or high blood pressure
• diabetes
• heart failure
• swelling of ankles or feet
• heartburn, indigestion, stomach ulcer or any other stomach problems
• bowel or intestinal problems
• vomiting blood or bleeding from the back passage
• chicken pox
• asthma or other difficulties with breathing
• runny or blocked nose, sneezing, facial pressure or pain
• dehydration
• liver or kidney disease
• tendency to bleed or other blood problems
• hay fever
• nasal polyps.

Tell your doctor or pharmacist if 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.

Tell your doctor or pharmacist if you plan to have surgery.

Tell your doctor or pharmacist if you are smoking.

If you have not told your doctor or pharmacist 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 medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking BRUFEN.

Some medicines may interfere with BRUFEN. These include:

• aspirin, salicylates or other NSAID medicines
• medicines used to prevent/stop blood clots such as warfarin or clopidogrel
• lithium, a medicine used to treat some types of depression
• medicines used to treat depression (SSRIs) such as fluoxetine
• medicines used to treat high blood pressure or other heart conditions
• diuretics, also called fluid tablets, medicines that increase the production of urine
• methotrexate, a medicine used to treat arthritis and some types of cancer
• corticosteroids used for inflammatory conditions, such as prednisone or cortisol
• medicines used to treat heart failure such as digoxin
• 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 improve memory
• quinolone antibiotics, medicines used to treat certain infections
• zidovudine, a medicine used to treat HIV
• cholestyramine, a medicine used to treat high cholesterol
• sulfonylureas, medicines to treat diabetes
• medicines used to treat certain fungal infections such as voriconazole or fluconazole
• mifepristone, a medicine used to terminate a pregnancy.

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

Your doctor and 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

Adults

For adults and children from 12 years, the usual dose of BRUFEN is 2 tablets at once, then 1-2 tablets every 4 hours as necessary (maximum of 6 tablets in 24 hours).

Children

For children aged 7-11 years, give 1 tablet every 6 to 8 hours as necessary (maximum 4 tablets in 24 hours).

Do not give BRUFEN to children under 7 years.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time(s) each day. Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food. Taking with food may help reduce the possibility of an upset stomach.

How long to take it

BRUFEN should not be used for more than 3 days at a time, except on medical advice.

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.

**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 medicine 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.

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**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 who treat 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. It may affect other medicines used during surgery. NSAID medicines can slow down blood clotting.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

If you get an infection while taking BRUFEN, 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.

**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. These include:

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

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

**Things to be careful of**

Be careful driving or operating machinery until you know how BRUFEN affects you. This medicine may cause dizziness, drowsiness, fatigue and visual disturbance in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, certain side effects may be worse.

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**In case of overdose**

**If you take too much (overdose)**

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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.

Symptoms of an overdose may include feeling sick or vomiting; stomach pain; convulsions; slow or fast heartbeat; ringing in your ears; headache; rapid, uncontrollable movements of the eyes; feeling drowsy; feeling dizzy or even becoming unconscious.

**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 with pain and inflammation, but it may have unwanted side effects in a few people.

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- nausea or vomiting
- loss of appetite
- heartburn or pain in the stomach
- cramps, wind, constipation or diarrhoea
- headache
- sleepiness
- dizziness
- buzzing or ringing in the ears or other trouble hearing
- runny or stuffy nose
- sleeplessness
- changes in mood, for example depression, confusion, nervousness
- hallucinations.

The above list includes side effects that 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
• loss of vision
• 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
• dark coloured urine
• 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
• fever
• unusual weight loss.

The above list includes serious side effects that may require medical attention. Serious side effects are less common.

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, chest tightness
• 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, extreme sensitivity to bright light.

BRUFEN may be associated with an increased risk of heart attack (myocardial infarction) or stroke.

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.

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 your tablets in a cool dry place where the temperature stays below 30°C.

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

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Dispersion

If the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BRUFEN 200 mg tablets are white, circular tablets with "IBU 200" embossed on one side and plain on the other side.

Ingredients

Active ingredient:
BRUFEN tablets contain 200 mg of ibuprofen as the active ingredient.

Inactive ingredients:
BRUFEN also contains:

• colloidal silica anhydrous
• maize starch
• stearic acid
• hypromellose
• titanium dioxide
• polyethylene glycol.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

BRUFEN comes in pack sizes of 30, 60, 100 tablets.

Not all pack sizes may be available.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

BRUFEN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 168 168

Date of Information

21 June 2019
(based on datasheet dated 21 June 2019).