

NEW ZEALAND CONSUMER MEDICINE INFORMATION

BRUFEN ONE®

Ibuprofen film-coated tablet 400 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Brufen One

This leaflet answers some common questions about Brufen One.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Brufen One is used for

Brufen One provides temporary relief of pain and/or inflammation associated with:

- Headache
- Migraine headache
- Tension headache
- Dental pain
- Backache
- Muscular pain
- Period pain
- Arthritic pain
- Sinus pain
- Cold & flu symptoms

Brufen One also relieves fever (high temperature).

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

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

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 or doctor.

This medicine is available only from your pharmacist or doctor's prescription.

Brufen One is not addictive.

Before you take Brufen One

When you must not take it

Do not take Brufen One 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 to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- stomach ache, fever, chills, nausea and vomiting
- fainting.

If you are allergic to aspirin or NSAID medicines and take

Brufen One, these symptoms may be severe.

Do not take Brufen One if you are in your third trimester of pregnancy.

It may affect your developing baby if you take it during this time.

Do not take Brufen One if you have (or have previously) vomited blood or material that looks like coffee grounds.

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

Do not take Brufen One 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 One if you have, or have a history of, ulcerative colitis or Crohn's disease.

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

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established for Brufen One.

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 pharmacist or doctor.

Before you start to take it

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

Tell your pharmacist or doctor if you are pregnant or plan to become pregnant or are breast-feeding or plan to breast-feed. Like most NSAID medicines, Brufen One is not recommended while you are pregnant or breast-feeding.

Tell your pharmacist or doctor 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 gastrointestinal problems
- vomiting blood or bleeding from the rectum (back passage)
- severe skin reactions such as Stevens-Johnson syndrome
- chicken pox
- asthma or hay fever
- other difficulties with breathing
- visual disturbances
- liver or kidney disease
- tendency to bleed or other blood problems
- aseptic meningitis
- if you drink alcohol
- runny or blocked nose, sneezing, facial pressure or pain
- if you feel dehydrated
- if you are a current smoker
- nasal polyps
- high cholesterol.

Tell your pharmacist or doctor if you currently have an infection. If you take Brufen One 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 pharmacist or doctor if you plan to have surgery.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking Brufen One.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get 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 One.

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

- aspirin, salicylates or other NSAID medicines
- warfarin or clopidogrel, medicines used to prevent/stop blood clots
- lithium, a medicine used to treat changes in mood and some types of depression
- SSRIs such as fluoxetine, medicines used to treat depression
- medicines used to treat high blood pressure or other heart conditions
- diuretics, also called fluid tablets
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- medicines used to treat heart failure or irregular heartbeats 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
- ginkgo 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
- voriconazole or fluconazole, medicines to treat certain fungal infections
- mifepristone, a medicine used to terminate a pregnancy.

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

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

How to take Brufen One

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

They may differ from the information contained in this leaflet.

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

How much to take

Adults and children from 12 years

Take one tablet (= 400 mg) every 4-6 hours as necessary (maximum of 3 tablets (=1200 mg) in 24 hours)

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

How to take it

Swallow the tablets whole with a full glass of water, with or without food.

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.

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.

How long to take it

Do not take Brufen One for more than 3 days.

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

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

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 pharmacist or doctor.

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

While you are using Brufen One

Things you must do

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

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 One, tell your pharmacist or doctor.

Brufen One 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 or pharmacist if, for any reason, you have not taken your medicine exactly as instructed. Otherwise your doctor or pharmacist may think that it was not effective and change your treatment unnecessarily.

Tell your doctor or pharmacist if you feel the medicine is not helping your condition. This will help your doctor or pharmacist to determine the best treatment for you.

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

Things you must not do

Do not take any other medicines to relieve pain and reduce inflammation while you are taking Brufen One without first telling your pharmacist or 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 One 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. Children should be careful when riding bicycles or climbing trees

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, certain side effects may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Brufen One. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Brufen One you may:

- feel sick or vomit
- have stomach pain
- have convulsions
- have a slow or fast heartbeat
- have ringing in your ears
- feel drowsy
- feel dizzy or even become unconscious
- vomit blood or material that looks like coffee grounds
- bleed from the rectum (back passage), black sticky bowel motions (stools) or bloody diarrhoea
- have a headache and/or experience rapid uncontrollable movements of the eyes.

Side effects

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

This medicine helps most people with pain and inflammation, 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 lists 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 or pharmacist 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 or drowsiness
- dizziness
- buzzing or ringing in the ears or other trouble hearing
- runny or stuffy nose
- sleeplessness (insomnia)
- feeling tired (fatigue).

These side effects are usually mild.

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

- hallucinations
- changes in mood, for example depression, confusion, nervousness
- 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
- 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.

The above list includes serious side effects that may require medical attention.

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 rectum (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 pain/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
- severe skin rash with fever.

- pustules (boils and abscesses) on the skin
- convulsions.

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

Blood disorders and kidney problems may occur with Brufen One.

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 anything that is making you feel unwell.

After using Brufen One

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 25°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.

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 it looks like

Brufen One 400 mg tablets are white, pillow shaped, film-coated tablets.

Ingredients

Brufen One tablets contain 400 mg of ibuprofen as the active ingredient.

They also contain:

- colloidal silicon dioxide
- croscarmellose sodium
- hypromellose
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- purified talc
- sodium laurilsulfate
- titanium dioxide.

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

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of Information

05 August 2020
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