

NEW ZEALAND CONSUMER MEDICINE INFORMATION

BRUFEN® EXTRA

200 mg ibuprofen and 500 mg paracetamol film coated tablet



What is in this leaflet

Please read this leaflet carefully before you start taking Brufen Extra.

This leaflet answers some common questions about Brufen Extra.

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 Extra is used for

Brufen Extra is used for the temporary relief of pain and/or inflammation associated with:

- headache
- migraine headache
- tension headache
- dental pain
- back pain
- muscular pain
- period pain
- rheumatic pain
- non-serious arthritic pain
- cold and flu symptoms
- sore throat.

Brufen Extra can also reduce fever.

Ask your doctor or pharmacist if you have any questions about Brufen Extra.

This medicine is available from pharmacies without a prescription.

This medicine is not addictive.

Before you take Brufen Extra

When you must not take it

Do not take Brufen Extra if you have an allergy to:

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

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.

Do not use this medicine if you are taking any other NSAID or aspirin unless instructed by your doctor. 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.

Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.

Do not take Brufen Extra if you are in your third trimester of pregnancy. Before taking Brufen Extra in the first two trimesters of pregnancy talk to your doctor or pharmacist.

Taking Brufen Extra during pregnancy may increase the risk of

miscarriage or affect the development of your baby.

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.

Do not take this medicine if you have heart failure and/or kidney disease.

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

Do not take Brufen Extra 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 Extra 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 this medicine if you drink excessive alcohol or suffer from alcoholism.

This may increase the risk of paracetamol causing liver damage.

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.

Before you start to take it

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

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

- chronic liver disease or history of liver disease
- kidney disease
- if you have a condition resulting in an increased tendency to bleed or other blood disorders
- high blood pressure or hypertension
- heart failure (symptoms included swelling of ankles or feet)
- diabetes
- high cholesterol
- current smoker
- if you feel dehydrated
- severe skin reaction reactions
- asthma or history of asthma.

Tell your doctor or pharmacist if you are over the age of 65.

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

Tell your doctor or pharmacist if you have been on a prolonged course of corticosteroid (“steroid”) therapy as this medicine needs to be tapered down slowly if Brufen Extra is added to the treatment plan.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

Like most NSAID medicines, Brufen Extra is not recommended while you are pregnant or breastfeeding.

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

Tell your doctor or pharmacist if you currently have an infection.

If you take Brufen Extra 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Brufen Extra.

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 Extra.

Some medicines may interfere with Brufen Extra. These include:

- SSRIs such as fluoxetine, medicines used to treat depression
- medicines used to thin the blood
- aminoglycosides, medicines used to treat certain infections
- cholestyramine, a medicine used to treat high cholesterol
- ginkgo biloba, a herbal medicine used to improve memory
- aspirin, salicylates or other NSAID medicines (including COX-2 inhibitors)
- ciclosporin or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection
- mifepristone, a medicine used to terminate a pregnancy
- quinolone antibiotics, medicines used to treat certain infections
- sulfonyleureas, medicines to treat diabetes
- other certain medicines used to treat diabetes
- voriconazole or fluconazole, medicines to treat certain fungal infections.
- anticoagulants (such as warfarin), medicines used to prevent/stop blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines that can delay contents being emptied from the stomach (gastric emptying) such as propantheline, certain antidepressants and medicines used to relieve pain (narcotics).
- chloramphenicol, an antibiotic used to treat ear and eye infections
- anticonvulsant agents -- medicines used to treat epilepsy or fits (such as phenytoin)
- probenecid, a medicine used to treat gout.
- isoniazid or other medicines used to treat tuberculosis
- zidovudine, a medicine used to treat HIV
- co-trimoxazole, a medicine used to treat certain infections
- lithium, a medicine used to treat some types of depression or changes in mood.
- medicines used to treat high blood pressure or other heart conditions (such as ace-inhibitors or beta blockers)
- diuretics, also called fluid tablets
- methotrexate, a medicine used to treat arthritis and some types of cancer
- medicines used to treat heart failure such as digoxin
- corticosteroids, such as prednisone, cortisone.

Tell you pharmacist or doctor if you drink alcohol.

These medicines may be affected by Brufen Extra 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 Extra

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 box, ask your doctor or pharmacist for help.

How much to take

Adults and adolescents from 12 years.

Take 1-2 tablets every 6-8 hours as necessary (maximum 6 tablets in 24 hours).

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.

How long to take it

Don't take Brufen Extra for longer than 3 days at a time unless advised by a 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 doctor or pharmacist.

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

While you are taking Brufen Extra

Things you must do

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

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.

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 Extra, tell your doctor or pharmacist. Brufen Extra 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 Extra without first telling your doctor or pharmacist. These include:

- other medicines containing ibuprofen, an active ingredient in Brufen Extra
- other medicines containing paracetamol, an active ingredient in Brufen Extra
- aspirin (also called acetylsalicylic acid)
- any other NSAID medicine.

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

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. Adolescents 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. Tell your pharmacist or doctor if you drink alcohol.

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 Extra. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many Brufen Extra tablets can lead to delayed, serious liver and renal damage.

If you take too much Brufen Extra you may:

- pale appearance;
- feel sick or vomiting;
- have stomach pain;
- have convulsions;
- have a slow or fast heartbeat;
- very slow breathing;
- have ringing in your ears;
- feel drowsy;
- feeling dizzy or even becoming unconscious;
- vomit blood or material that looks like coffee grounds;
- bleed from the rectum (back passage), black sticky

- bowel motions (stools) or bloody diarrhoea;
- lack of co-ordination;
- slurred speech.

Side effects

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

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
- indigestion – an uncomfortable feeling in the stomach or belching after eating
- heartburn or pain in the upper part of your stomach
- cramps, wind, or constipation
- diarrhoea
- headache
- dizziness or drowsiness
- sleepiness
- strange dreams
- buzzing or ringing in the ears or other trouble hearing
- sleeplessness
- bloating or flatulence
- feeling tired
- hair loss
- sneezing or blocked nose
- nose bleeds
- heavy periods
- tingling of the hands and

feet

The above list includes side effects that are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- changes in mood, for example depression, confusion, nervousness or anxiety
- hallucinations
- 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
- unusual weight gain
- swelling of ankles or legs

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

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

- yellowing of the skin and/or eyes, also called jaundice
- 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
- palpitations or rapid heartbeat
- blistering, rash, hives, peeling, fluid or pus-filled skin lesions, mouth lesions, or painful red areas of skin.

They may be accompanied by fever, chills, aching muscles and generally feeling unwell.

- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.
- Pustules (boils and abscesses) on the skin
- Fever, rash, lymph node enlargement
- Convulsions
- Reduced level of consciousness
- Generalised weakness

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

Blood disorders may occur with Brufen Extra.

Taking Brufen Extra for a long time at higher than recommended dose* or overdosing may result in problems with your kidneys and low potassium levels in your blood.

*The risk is increased with higher doses of ibuprofen and following acute overdose, however it may also occur within the recommended dose range.

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 that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor 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 taking Brufen Extra

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 Extra 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 or pharmacist 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 Extra tablets are a white to off-white, oval shaped, biconvex, film-coated pearlescent tablet, plain on both sides.

Brufen Extra comes in blister packs of 36 or 60 film coated tablets.

Ingredients

Active ingredients:

Brufen Extra contains 200 mg of ibuprofen and 500 mg of paracetamol as the active ingredients.

Inactive ingredients:

Brufen Extra also contains:

- colloidal silicon dioxide
- crospovidone
- hypromellose
- magnesium stearate
- microcrystalline cellulose

- opadry silver special effects 63F97546
- povidone
- pregelatinized maize starch
- purified talc
- purified water
- titanium dioxide

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 Extra is supplied in New Zealand by:

Viatrix Ltd,
PO Box 11-183,
Eilerslie,
Auckland
www.viatrix.co.nz
Telephone: 0800 168 169

Date of Preparation

23 July 2024
(Based on datasheet dated 23 July 2024)

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