

BREN 400 & 200 mg TABLETS

Ibuprofen

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine is prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What **BREN** Tablets is & what is it they are used for

BREN Tablets belongs to a group of medicines called anti-inflammatory pain killers. They can be used to relieve pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, ankylosing spondylitis, swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

BREN Tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

BREN Tablets can be used in treatment of fevers.

The active ingredient in BREN Tablets is ibuprofen and each tablet contains either 400 or 200 mg of Ibuprofen

2. Before you take BREN Tablets

Do not take BREN Tablets

- If you are pregnant or planning to become pregnant, or you are breast-feeding.
- If you are sensitive (allergic) to any of the ingredients in the tablets or any of the other ingredients listed in Section 6.
- If you have, or have you previously had, a stomach ulcer or other gastric complaint
- If you currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past.
- If you have a condition which increases your tendency to bleeding?
- If you suffer from asthma or have you ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or other anti-inflammatory pain killers?
- If you suffer from swelling and irritation inside the nose?
- If you suffer from liver or kidney disease?
- If you suffer from heart disease?

Take special care with BREN Tablets

- If you suffer from heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries).
- If you had any kind of stroke or think that you might be at risk of these conditions (e.g. if you have a family history of heart disease or stroke, high blood pressure, diabetes, high cholesterol or are a smoker).
- If you have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)?
- If you have chicken pox or shingles?
- If you or your child is dehydrated, as there is a risk of kidney damage in dehydrated children adolescents and the elderly.
- if you have an infection – please see heading ‘Infections’

Skin reactions

Serious skin reactions have been reported in association with Bren Tablets treatment. You should stop taking Bren Tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction.

Infections

Bren tablets may hide signs of infections such as fever and pain. It is therefore possible that Bren tablets may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Taking other medicines with BREN Tablets

Please tell your doctor, or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlodipine),
- some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan)
- diuretics (e.g. Hydrochlorothiazide)
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- medicines known as immunosuppressants such as ciclosporin and tacrolimus (used to dampen down your immune response)
- medicines known as selective serotonin reuptake inhibitors (SSRIs), used for the treatment of depression
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- mifepristone
- any other ibuprofen, such as those you can buy without a prescription
- any other anti-inflammatory pain killer, including aspirin
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Taking BREN Tablets with Alcohol: BREN Tablets may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with BREN might make these side effects worse.

Taking BREN Tablets with food and drink:

Take ibuprofen tablets with a meal or snack, or with a drink of milk. It will be less likely to upset your stomach. If you take it just after food, ibuprofen may take longer to start working.

Pregnancy and breast-feeding: The use of BREN whilst pregnant or breast feeding should be avoided. BREN should not be used in late (the last three months of) pregnancy and should only be taken in the first six months of pregnancy on the advice of your doctor.

Driving and Using Machines:

Do not drive because BREN may make you feel dizzy or drowsy.

Do not use any tools or machines because BREN may make you feel dizzy or drowsy.

Important information about some of the ingredients of BREN Tablets

BREN contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3.How to take Bren Tablets?

ALWAYS take BREN Tablets exactly as your doctor has told you. If you are not sure refer to the label on the carton or check with your doctor or pharmacist.

Adults and children over 12 years

The usual dosage is 600 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for; but no more than 2400 mg should be taken in one day.

Children

- Pain and fever in children, child 1-4 years, 100 mg 3 times daily (max 30 mg/kg daily in 3-4 divided doses);
- Child 4-7 years, 150 mg 3 times daily (max 30mg/kg daily in 3-4 divided doses);
- Child 7-10 years, 200 mg 3 times daily (up to 30mg/kg daily max 2.4 g in 3-4 divided doses);
- Child 10-12 years, 300 mg 3 times daily (up to 30mg/kg) daily max 2.4g in 3-4 divided doses
- Rheumatic disease in children (including juvenile idiopathic arthritis)

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen.

If you take more BREN Tablets than you should

If you have taken more BREN Tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

IF YOU FORGET TO TAKE YOUR BREN TABLETS take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Never double up on a dose to make up for the one you have missed.

If you stop taking BREN Tablets

If you have any further questions on the use of this product, ask your doctor or pharmacist

4. Possible side effects of Bren Tablets

As with all medicines, Bren Tablets may cause side effects, although they are usually mild and not everyone will suffer from them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

STOP TAKING Bren Tablets and seek immediate medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light.

- Signs of intestinal bleeding such as
 - Passing blood in your faeces (stools/motions)
 - Passing black tarry stools
 - Vomiting any blood or dark particles that look like coffee grounds

TELL YOUR DOCTOR AND STOP TAKING BREN TABLETS IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting.

- Unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction).

- Loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations).
- Severe spreading skin rash ('Stevens-Johnson Syndrome', 'toxic epidermal necrolysis' and 'erythema multiforme', symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness)

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

Medicines such as Bren Tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction), stroke or heart failure.

Medicines such as Bren Tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles

Blood disorders such as reduction in blood cells and platelet counts – the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin. Kidney problems such as reduced kidney function, fluid retention (oedema), inflammation of the kidney and kidney failure. Liver problems such as inflammation of the liver, reduced liver function and yellowing of the eyes and/or skin (jaundice) or severe skin reactions may occur rarely with ibuprofen.

Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects

Common (affects up to 1 in 10 people):

- feeling dizzy or tired
- diarrhoea, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (affects up to 1 in a 100 people):

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- skin becomes sensitive to light
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)
- mouth ulcers

Rare (affects up to 1 in a 1000 people):

- feeling depressed or confused

Very rare (affects up to 1 in 10,000 people):

- inflammation of the pancreas

Not known (cannot be estimated from the available data):

- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Bren Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to medicalaffairs@kopran.com

5. How to store Bren Tablets?

Keep out of reach and sight of children

Do not store above 30°C. Protect from light. Store in original container.

Do **NOT** take Bren Tablets after the 'expiry' EXP date shown on the container. The expiry date refers to the last day of the month.

Do **NOT** take BREN Tablets if you notice visible signs of deterioration

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information about Bren Tablets

What BREN Tablets contain

The active substance in BREN Tablets is Ibuprofen available as 400 or 200 mg per tablet.

The other ingredients are : Starch, Talc, Magnesium Stearate/stearic acid, Silica, Sodium Lauryl Sulphate, Sodium Starch Glycollate, Hydroxypropyl Methylcellulose (HPMC), Titanium Dioxide , Colour Erythrosine Lake, Triacetin.

What BREN Tablets look like and contents of the pack

BREN-200: are presented as Pink colored, Circular, Slightly Biconvex, Coated Tablets.

BREN-400: are presented as Pink colored, Circular, Slightly Biconvex, Coated Tablets.

Following Packs are available for Bren Tablets

Alu/Pvc blister packs of 10x10Tabs.

Jar Pack of 500's Tabs, 1000's Tabs, 5000's Tabs.

Marketing Authorisation Holder:

Kopran Limited,

Address: 1076, Parijat House, Dr. E. Moses Road, Worli, Mumbai - 400 018, Maharashtra, India,

Manufacturer



Kopran Limited,

Address: Village Savroli, Taluka Khalapur, District Raigad – 410202, Maharashtra, India

For any information about this medicinal product, please contact below local representative

Country Name : Rwanda

Address : Phillips Pharmaceuticals (Rwanda) Ltd , GF 68, Kigali Modem City Market Commercial Street, Kigali, Rwanda B.P. 5671 Kigali, Rwanda.

Email: regulatory@phillipsrwanda.com

Country Name : Tanzania

Address : M/s Samiro Pharmacy Limited

P.O.BOX 38062, Lindi street, Kariakoo Dar -Es- Salaam, TANZANIA

Email: regulatory@samiropharma.co.tz

Country Name : Mozambique

Address : M/s, Afri Farmacia LDA At No. 1277, Av. Das FPLM, Maputo, Mozambique.

Email: registoafri@gmail.com

Country Name : Ethiopia
Address : Aschalew Bekele Health Consulting
Addis Ababa, Ethiopia, Email: info@aschalewbekelehealthconsulting.com

Country Name : Malawi
Address : Artemis Pharmaceuticals Limited.
Salim Amour Rd, Plot BE 175, Opp. Fattani Printers, Ginnery Corner, Blantyre P.O. Box 896,
Lilongwe, Blantyre, Malawi.
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