

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 01/2010

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: BRUFEN Tablets 200

Active ingredient: Ibuprofen

Dosage form: white tablet, diameter: 10.2 mm, thickness: 5.8 mm

Imprint or print on wrapping: ブルフェン 200, BRUFEN200, ky22, 200mg



Effects of this medicine

This medicine suppresses inflammation and shows actions to relief pain and fever (antiinflammatory and analgesic) by inhibiting synthesis of prostaglandin.

It is usually used for antiinflammation and pain relief in rheumatoid arthritis, joint pain and arthritis, neuralgia and neuritis, low back pain, cervicobrachial syndrome, and after surgeries and injuries. It is also used for antipyresis and pain relief in acute upper respiratory tract inflammation. It is usually used as a symptomatic treatment.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: gastric or duodenal ulcer, blood abnormality, hepatic disorder, renal disorder, cardiac dysfunction or hypertension.
If you have aspirin-induced asthma or a history of it.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For antipyresis and pain relief in acute upper respiratory tract inflammation: In general, for adults, take 1 tablet (200 mg of the active ingredient) at a time as needed. Avoid taking it on an empty stomach. The dosage may be adjusted according to the age or symptoms, however, it is limited to twice daily and the maximum daily dose is restricted to 3 tablets (600 mg).
For antiinflammation and pain relief in diseases other than acute upper airway inflammation: In general, for adults, take 1 tablet (200 mg of the active ingredient) at a time, three times daily. Avoid taking it on an empty stomach. For children aged 5 to 7 years, take 200–300 mg of the active ingredient; 8 to 10 years, take 300–400 mg of the active ingredient; 11 to 15 years, take 400–600 mg of the active ingredient; daily in three divided doses, respectively. The dosage may be adjusted according to the age or symptoms.
One tablet of this medicine contains 200mg of the active ingredient. Strictly follow the instructions in any case.
- If you miss a dose, take a dose as soon as you remember. However, wait about 4 hours to take the next dose. Even when you take this medicine for throat pain and antipyresis, wait about 4 hours to take the next dose. When you do not feel a severe pain and if it is 2 to 3 hours or less before the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include gastric discomfort, loss of appetite, abdominal pain, nausea, vomiting, rash, itch, facial swelling, hives, eczema and purpura. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- cold sweat, breathing difficulty, hives [shock, anaphylactoid symptoms]
- fever, headache, consciousness clouding [aseptic meningitis]
- high fever, conjunctival hyperemia, redness in large area of skin [oculomucocutaneous syndrome, toxic epidermal necrolysis]
- oliguria, swelling [acute renal failure, interstitial nephritis, nephrotic syndrome]
- wheezing, breathing difficulty [asthmatic attack]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your

doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.