FRONT

BUPROL-B TABLET

VIBUP06-0 (MY)

Description
Round, pink coated tablet with shallow convex faces, bevel-edged and HD embossed on one face.

Composition
Ibuprofen 400 mg/tablet
This product contains Ponceau 4R as colouring agent.

Actions and Pharmacology
Ibuprofen has analgesic, anti-inflammatory and antipyretic actions. Being a prostaglandin synthesis and action inhibitor, it is also effective in relieving dysmenorrhoea.

It is well absorbed from the gastrointestinal tract and is extensively bound to plasma proteins. It undergoes hepatic metabolism and primarily renal excretion.

Indications
For relief of :
- Acute and chronic rheumatoid arthritis and osteoarthritis.
- Mild to moderate pain arising from dental, obstetric or orthopaedic surgery, soft tissue injuries and primary dysmenorrhoea.

Contraindications
It should not be used in the following conditions:
Symptoms of nasal polyps associated with bronchospasm or angioedema, anaphylaxis or other severe allergic reactions induced by aspirin or other NSAIDs.
It should not be used in patients who have previously exhibited hypersensitivity to it or in individuals hypersensitive to aspirin or other non-steroidal anti-inflammatory agents. Anaphylactoid reactions have occured in such patients.

Warning
RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (eg. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (eg. alcoholism, smoking, corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Precautions
- Caution in patients with anaemia or asthma, gastrointestinal toxicity, hypertension, congestive heart failure, diabetes mellitus, preexisting edema, extracellular volume depletion or sepsis, hemophilia or other bleeding problems, hepatic function impairment, renal function impairment, stomatitis, symptoms of bronchospasm, allergic rhinitis, urticaria, induced by aspirin or other NSAIDs, systemic lupus erythematosus (SLE).
- Blurred and/or diminished vision, scotomata, and/or changes in colour vision have been reported. If a patient developes such complaints while receiving Buprol-B, the drug should be discontinued and the patient should have an opthalmologic examination which includes central visual fields and colour visions testing.
- Fluid retention and edema have been reported in association with Buprol-B, therefore, the drug should be used with caution in patients with a history of cardiac decompensation or hypertension.
- Buprol-B, like other nonsteroidal anti-inflammatory agents, can inhibit platelet aggregation but the effect is quantitatively less and of shorter duration than that seen with aspirin. Ibuprofen has been shown to prolong bleeding time (but within the normal range), in normal subjects.
- Because this prolonged bleeding effect may be exaggerated in patients with underlying hemostatic defects, Buprol-B should be used with caution in persons with intrinsic coagulation defects and those on anticoagulant therapy.
- Patients on Buprol-B should report to their physicians signs or symptoms of gastrointestinal ulceration or bleeding, blurred visions or other eye symptoms, skin rash, weight gain, or edema.
- In order to avoid exacerbation of disease or adrenal insufficiency, patients who have been on prolonged corticosteroid therapy should have their therapy tapered slowly rather than discontinued abruptly when Buprol-B is added to the treatment program.

BACK

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- The antipyretic and anti-inflammatory activity of ibuprofen may reduce fever and inflammation, thus diminishing their utility as diagnostic signs in detecting complications of presumed noninflammatory painful conditions.
- Patients hypersensitive to aspirin, to one of the non-steroidal anti-inflammatory agents, or to related analgesic agents may be hypersensitive to ibuprofen.
- Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, if possible, be avoided. In the limited studies so far available, ibuprofen appears in the breast milk in verly low concentration and is unlikely to affect the breast-fed infant adversely.
- Safety and efficacy for use as an antipyretic in infants younger than 6 months of age, or for use as an antirheumatic in infants younger than 12 months of age, have not been established.
- Caution is recommended in geriatric patients, who may be more likely to develop adverse hepatic or renal effect with the medication and in whom gastrointestinal ulceration or bleeding is more likely to cause serious consequences, including fatalities.

Pregnancy and Lactation

- Whilst no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, if possible, be avoided.
- In the limited studies so far available, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

Main Side/Adverse Effects

- Frequent incidences include gastrointestinal bleeding and peptic ulceration, other gastrointestinal effects - mild to moderate abdominal or stomach cramp, pain or discomfort, heartburn or indigestion, nausea, diarrhoea, constipation, decreased appetite or loss of appetite, skin rash.
- Less frequent to rare incidences include headache, dizziness, nervousness, pruritus, tinnitus, depression, oedema, drowsiness, insomnia, blurred visions and other ocular reactions, hypersensitivity reactions, abnormalities of liver function test, impairment of renal function.

Drug Interactions

Caution in patients receiving the following drug therapy:
Acetaminophen, Potassium supplements, Aminoglycosides or Digitalis glycosides, Anticoagulant, coumarin-or indandione-derivative, or heparin or thrombolytic agents, Antidiabetic agents or Insulin, Antihypertensive or Diuretics, Aspirin, Colchicine, Nifedipine or Verapamil, Probenecid, Methotrexate and Lithium.

Overdosage

Clinical features: Gastrointestinal irritation or ulceration, constipation, skin rashes, dizziness, fluid retention, amblyopia, leukopenia and anemia.

Treatment of overdosage consists of emesis or gastric lavage, administration of activated charcoal and antacids, and monitoring and supporting vital functions. Induction of diuresis may be useful.

Dosage and administration

Adults and children over 12 years:
Rheumatoid arthritis, osteoarthritis and allied conditions:
Oral, 1200 – 1600mg daily in three or four divided doses, or as directed

Note: The information given here is limited. For further information consult your doctor or pharmacist.

Storage : Store below 30°C. Protect from light and moisture.
Presentation/Packing : Film-coated tablet blisters of 10 x 10's.

Product Registration Holder : HOVID Bhd.,121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.
Manufactured by : HOVID Bhd., Lot 56442, 7 1/2 Miles, Jalan Ipoh / Chemor, 31200 Chemor, Malaysia.

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