Purifen®

Dexibuprofen 200, 300 & 400 mg tablet

Presentation
Purifen 200 tablet: Each film-coated tablet contains 200 mg Dexibuprofen INN.
Purifen 300 tablet: Each film-coated tablet contains 300 mg Dexibuprofen INN.
Purifen 400 tablet: Each film-coated tablet contains 400 mg Dexibuprofen INN.

Description
Dexibuprofen (S (+)-ibuprofen) is considered as the pharmacologically active enantiomer of racemic ibuprofen. Like racemic ibuprofen, Dexibuprofen is a non-steroidal anti-inflammatory drug with analgesic action. Like ibuprofen, Dexibuprofen acts by inhibiting prostaglandin synthesis.

Indications
- Indicated for the relief of sign and symptoms of osteoarthritis.
- Indicated in rheumatoidal disorders such as osseous rheumatism, ankylosing spondilitis, juvenile arthritis, muscular rheumatism, degenerative joint diseases.
- Acute symptomatic treatment of painful menstruation (primary dysmenorrhoea).
- Common headache and fever
- Symptomatic treatment of mild to moderate pain, such as muscle pain, headache and dental pain
- As adjuvant with common cold and influenza associated with headache.

Dosage and Administration
The dosage must be adjusted to the seriousness of the syndrome and the complaints of the patient. During chronic pain, the dosage must be adapted to the lowest effective dose.

The recommended dosage is 600-900 mg Dexibuprofen per day, at 2-3 divided doses. The dosage can be raised temporarily up to 1200 mg Dexibuprofen per day in patients with acute disorders or exacerbations. The maximum daily dose is 1200 mg.

At dysmenorrhea, a dosage of 600 up to 900 mg Dexibuprofen per day, at divided dose.

At elderly people, lowest effective dose is recommended. The dosage can be raised to adult dosage if well tolerated.

Hepatic impairment: Patients with mild to moderate liver function impairments must start with low amounts, and must closely be monitored. Dexibuprofen should not be used in patients with serious liver function impairments.

Renal impairment: The start amount must be reduced at patients with mild to moderate kidney function impairments. Dexibuprofen cannot be used patients with serious kidney function impairments.

Side-effects
Clinical experience has shown that adverse effects of Dexibuprofen are similar to those of racemic ibuprofen. Common side-effects are dyspepsia, diarrhea, fatigue, and headache, nausea, vomiting, abdominal pain.

Precautions
Dexibuprofen should be used with particular caution in patients with bronchial asthma or other chronic diseases of the pulmonary tract as well as in persons prone to allergy. The drug should be used in patients with hepatic, renal or cardiac insufficiency and with hypertension not responding to any treatment. Consultation with a doctor is recommended for patients with systemic lupus or with other autoimmunological disease before beginning therapy using the drug. Dexibuprofen should be used with extreme cautions in active and suspected hemorrhagic conditions such as gastro-duodenal ulcers, ulcerative colitis, crohn's disease, alcoholism. Allergic reactions to the drug may appear even for the first time user and in such case it should immediately be stopped.

Use in pregnancy and lactations
Pregnancy: Although no teratogennic impact has been observed in the animal-experimental research with dexibuprofen or ibuprofen, the use should be avoided during the pregnancy. However, animal reproduction studies are not always predictive of human response. Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during late pregnancy should be avoided.

Lactation: Studies at people have shown that racimic ibuprofen proceed in small to negligible degree in mother milk. So, Dexibuprofen should be used with cautions in nursing mothers.

Contraindications
Dexibuprofen is contraindicated in patients with previous history of hypersensitivity to Dexibuprofen, or another NSAID, or any other component of the product. Patients, who experience attack of asthma, arouse bronchospasm, acute rhinitis, urticaria or edema after use of similar drugs (e.g. aspirin or other NSAID's). It is also contraindicated in patients with active or suspected hemorrhage, Crohn's disease or ulcerative colitis, patients with serious heart diseases, kidney function impairment (GFR < 30ml/min), and liver function impairment.

Drug Interactions
The reported drug interactions of Dexibuprofen are similar to that of racemic mixture of ibuprofen. Drug interactions is noticed with simultaneous use of anticoagulant, hydantoine and sulfonamide, ticlopidine, lithium, other NSAID's, ACE inhibitors, beta blockers, cyclosporine, tacrolimus, corticosteroids, digoxin, methotrexate, pentoxyfiline, phenytoine, probenecid, sulfinpyrazon, sulfonylurea, thiazide and thiazide type diuretics, and zidovudine.

Overdose
Dexibuprofen have low acute toxicities. Symptoms of toxicity occur at doses between 80 and 100 mg/kg body weight. Mild symptoms are abdominal pain, nausea, vomiting, lethargy, headache, tinnitus and ataxia. Moderate to serious symptoms, such as flatulence, hypotension, hypothermia, metabolic acidosis, reduced kidney function, coma, and apnoea.
The treatment must be symptomatic; there is no specific antidote. In case of large quantities of Dexibuprofen, activated charcoal should be administered.
Vomiting can be induced only when life-threatening quantities of the substance ingested and the procedure can be carried out within 60 minutes after ingested. Dialysis and hemodialysis are of little value as Dexibuprofen binds strongly to plasma protein.

Commercial Pack
Purifen 200 tablet: Each box contain 5 alu-alu blister strips of 4 tablets.
Purifen 300 tablet: Each box contain 5 alu-alu blister strips of 4 tablets.
Purifen 400 tablet: Each box contain 5 alu-alu blister strips of 4 tablets.

Manufactured by

Incepta Pharmaceuticals Ltd
Dhaka, Bangladesh