

## COMPOSITION

Xflam ® 200 Tablet: Each film-coated tablet contains Dexibuprofen INN 200 mg.

Xflam ® 300 Tablet: Each film-coated tablet contains Dexibuprofen INN 300 mg.

Xflam ® 400 Tablet: Each film-coated tablet contains Dexibuprofen INN 400 mg.

## PHARMACOLOGY

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.

## INDICATION

Management of pain & inflammation associated with osteoarthritis and other musculoskeletal disorders.

Symptomatic treatment of mild to moderate pain and inflammation including dysmenorrhoea and dental pain.

## DOSAGE & ADMINISTRATION

The recommended dosage is 600-900 mg Dexibuprofen per day, at 2-3 divided doses. Maximum single dose is 400 mg. The dosage can be raised temporarily up to 1200 mg Dexibuprofen per day in patients with acute disorders or exacerbations.

Children: As the molecule's safety and efficacy has not been established in patients under 18 years of age, it cannot be recommended in this age group.

Elderly patient: Lowest effective dose is recommended. The dosage can be raised to adult dosage if well tolerated.

Hepatic impairment patient: 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 impairment.

Renal impairment patient: The starting amount must be reduced to patients with mild to moderate kidney function impairments. Dexibuprofen should not be used patients with serious kidney function impairments.

## CONTRAINDICATION & PRECAUTION

Dexibuprofen is contraindicated in patients with previous history of hypersensitivity to Dexibuprofen or other NSAIDs. Dexibuprofen is contraindicated in patients, who experience attack of asthma, bronchospasm, acute rhinitis, urticaria or edema after use of similar drugs (e.g., aspirin or other NSAIDs). 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 severe liver function impairment.

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 with caution in patients with hepatic, renal or cardiac insufficiency and with hypertension. Consultation with a doctor is recommended for patients with systemic lupus or with other autoimmunological diseases 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 reaction to the drug may appear even for the first time user and in such case it should immediately be stopped.

#### SIDE EFFECT

Clinical experience has shown that adverse effects of Dexibuprofen are similar to those of racemic Ibuprofen.

Common side effects: Dyspepsia, diarrhea, fatigue, and headache, nausea, vomiting, & abdominal pain.

Less common side effects: Flatulence, urticaria, pruritus, purpura, rhinitis, bronchospasm, insomnia, & tinnitus.

Rare side effects: Constipation, esophagitis, esophageal constrictions, exacerbation nonspecific hemorrhagic colitis, ulcerative colitis and Crohn's disease, anemia and haematemesis, anaphylactic shock, agitation, irritation, depression, thrombocytopenia, leucopenia, granulocytopenia, aplastic anemia or hemolytic anemia, & peripheral edema.

#### DRUG INTERACTION

The reported drug interactions of Dexibuprofen are similar to that of racemic Ibuprofen. Drug interactions is noticed with simultaneous use of anticoagulant, hydantoine and sulfonamide, ticlopidine, lithium, other NSAIDs, ACE inhibitors, beta blockers, cyclosporine, tacrolimus, corticosteroids, digoxin, methotrexate, pentoxifyline, phenytoine, probenecid, sulfinpyrazon, sulfonyleurea, thiazide and thiazide type diuretics, and zidovudine.

#### USE IN PREGNANCY AND LACTATION

Pregnancy: Although no teratogenic impact has been observed in the animal-experimental research with Dexibuprofen and Ibuprofen, use of Dexibuprofen should be avoided during the pregnancy.

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

#### STORAGE

Store in a cool & dry place protected from light and moisture. Keep out of reach of children.

#### HOW SUPPLIED

Xflam ® 200 Tablet Box containing 15 x 4 tablets in blister pack.

Xflam ® 300 Tablet Box containing 12 x 4 tablets in blister pack.

Xflam ® 400 Tablet Box containing 12 x 4 tablets in blister pack.