

Flamex[®]

Ibuprofen BP

Composition

Flamex[®] 200 Tablet: Each coated tablet contains Ibuprofen BP 200 mg.

Flamex[®] 400 Tablet: Each coated tablet contains Ibuprofen BP 400 mg.

Flamex[®] Suspension: Each 5 ml contains Ibuprofen BP 100 mg.

Flamex[®] SR Capsule: Each sustained release capsule contains Ibuprofen BP 300 mg.

Pharmacology

Flamex[®] is the preparation of Ibuprofen which is an NSAID, works by blocking the synthesis of prostaglandins and therefore reduces pain and inflammation. **Flamex[®]** tablet is the immediate release formulation of Ibuprofen and **Flamex[®] SR** capsule is a sustained release formulation of Ibuprofen. **Flamex[®] SR** capsule provides more prolonged analgesic & anti-inflammatory effect than immediate release Ibuprofen.

Indication

Flamex[®] is indicated for:

- Relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis
- Treatment of primary dysmenorrhea
- Control of pain generally and particularly when pain is associated with inflammation
- Reduction of fever

Flamex[®] SR is indicated for:

- Relief of backache
- Rheumatic pain
- Muscular pain

Dose and administration

Route of administration: **Flamex[®]** can be taken orally.

Adults and children over 12 years:

Flamex[®]

- Rheumatoid arthritis and osteoarthritis: Initially 300-400 mg 3-4 times daily; increased if necessary to maximum 2.4 g daily; maintenance dose of 0.6-1.2 g daily may be adequate.
- Analgesic and antipyretic: 200 to 400 mg every four to six hours as needed.
- Dysmenorrhea: 200 to 400 mg every four to six hours as needed. Dose should not exceed 3200 mg per day.

Flamex[®] SR

Initially one (300 mg) or two (600 mg) capsules should be taken twice daily. Not more than 4 capsules are to be taken in 24 hours.

In children:

Flamex[®]

Mild to moderate pain, pain and inflammation of soft tissue injuries, pyrexia with discomfort

Child 1-3 months: 5 mg/kg 3-4 times daily

Child 3-6 months: 50 mg 3 times daily (maximum 30 mg/kg daily in 3-4 divided doses)

Child 6 months-1 year: 50 mg 3-4 times daily (maximum 30 mg/kg daily in 3-4 divided doses)

Child 1-4 years: 100 mg 3 times daily (maximum 30 mg/kg daily in 3-4 divided doses)

Child 4-7 years: 150 mg 3 times daily (maximum 30 mg/kg daily in 3-4 divided doses)

Child 7-10 years: 200 mg 3 times daily (up to 30 mg/kg daily (maximum 2.4 g) in 3-4 divided doses)

Child 10-12 years: 300 mg 3 times daily (up to 30 mg/kg daily (maximum 2.4 g) in 3-4 divided doses)

Rheumatic disease in children

Child 3 months-18 years: 30-40 mg/kg (maximum 2.4 g) daily in 3-4 divided doses; in systemic juvenile idiopathic arthritis up to 60 mg/kg (maximum 2.4 g) daily in 4-6 divided doses.

Post immunization pyrexia in infants

Child 2-3 months: 50 mg as a single dose repeated once after 6 hours if necessary.

Flamex® SR is not recommended for children under 12 years of age.

Elderly:

No special dosage modifications are required for elderly patients unless there is an impairment of renal or hepatic function. In case of such impairment, the dosage should be assessed individually by the physician.

Contraindication

Ibuprofen is contraindicated to the patients with known hypersensitivity to this drug. It is also contraindicated in patients with a history of peptic ulceration. Bronchospasm may be precipitated in patients suffering from, or with a previous history of bronchial asthma or allergic disease. Ibuprofen should not be given to patients in whom aspirin or other NSAIDs induce the symptoms of asthma, rhinitis or urticaria.

Warning and precaution

Ibuprofen should be given with caution to patients with bleeding disorders, cardiovascular diseases, peptic ulceration or a history of such ulceration, in those receiving coumarin anticoagulants and in patients with renal or hepatic impairment.

Side effects

The side effects of ibuprofen may include dyspepsia, gastro-intestinal intolerance and bleeding and skin rashes of various types. Less frequently, thrombocytopenia has occurred.

Use in pregnancy and lactation

Pregnancy: Although no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, if possible, be avoided.

Lactation: In the limited studies so far available, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breastfed infant adversely.

Drug interaction

Drug interaction with medication: In therapeutic doses there is no evidence of significant interactions with other commonly used drugs. However, caution should be exercised in patients receiving oral anticoagulants and thiazide diuretics.

Drug interaction with food and others: Not applicable

Overdose

In case of overdose, gastric lavage and if necessary, correction of serum electrolytes have been recommended. There is no specific antidote for ibuprofen.

Storage

Store below 30°C in a dry place, protected from light. Keep away from the reach of children.

Packing

Flamex® 200 Tablet: Carton of 100 tablets in blister pack.

Flamex® 400 Tablet: Carton of 100 tablets in blister pack.

Flamex® Suspension: Bottle of 100 ml.

Flamex® SR Capsule: Carton of 50 capsules in blister pack.

® Registered Trade Mark



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