

# KALFEN 400

## IBUPROFENO BP 400 MG COMPRIMIDO

**Composition:** Each film-coated tablet contains:

Ibuprofen B.P. 400 mg

Excipients q.s.

Color: Approved color used.

**Dosage:** As directed by a physician.

**Indications:** Ibuprofen provides relief from moderate pain in conditions such as dysmenorrhea and migraine, post-operative pain, and rheumatic pain—including ankylosing spondylitis, osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis), and other musculoskeletal disorders such as sprains and strains.

### **Contraindications:**

Ibuprofen is contraindicated in the following conditions:

- 1) Bronchospasm
- 2) Known sensitivity to aspirin
- 3) Peptic ulcer
- 4) Recent gastrointestinal hemorrhage
- 5) Renal insufficiency
- 6) Treatment of hypertension

**Pharmacological Actions:** Propionic acid derivatives are effective inhibitors of cyclooxygenase, the enzyme responsible for the biosynthesis of prostaglandins. All these agents alter platelet function and prolong bleeding time. Ibuprofen is well absorbed following oral administration. Ibuprofen is rapidly metabolized and eliminated via urine. Excretion of ibuprofen is nearly complete within 24 hours after the last dose. The serum half-life is 1.8 to 2.0 hours.

**Precautions and Warnings:** Bronchospasm may be precipitated in patients suffering from, or with a prior history of, bronchial asthma. Ibuprofen should not be administered to patients in whom aspirin or other non-steroidal anti-inflammatory drugs induce symptoms of asthma, rhinitis, or urticaria. Blurred or diminished vision has been reported; if a patient develops such complaints while taking ibuprofen tablets, use of the medication should be discontinued. The medication should be used with caution in patients with a history of cardiac decompensation or hypertension.

**Adverse Effects:** Common side effects associated with ibuprofen include gastrointestinal disturbances. Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include dizziness, nervousness, skin rash, tinnitus, edema, depression, blurred vision, drowsiness, and other common reactions.

### **Dosage and Administration:**

**Adults:** A starting dose of 1200–1800 mg per day, administered in divided doses, is recommended. Some patients may be maintained on 600–1200 mg per day. In severe conditions, it may be advantageous to increase the dose; however, the total daily dose should not exceed 2400 mg, administered in divided doses.

**Children:** Daily dose: 20 mg/kg of body weight, administered in divided doses. For juvenile rheumatoid arthritis, doses of up to 40 mg/kg of body weight, administered in divided doses, may be used. For children weighing less than 30 kg, the total dose within a 24-hour period should not exceed 500 mg.

**Storage:** Store below 30°C in a dry place; protect from light.

**Presentation:** A package containing 10 blister packs of 10 tablets each, and 5 blister packs of 50 tablets each.

**Keep all medicines out of the reach of children.**

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