

# DAPROFEN®

## Ibuprofen Tablets and Suspension

### Composition:

**Suspension:** Each 5ml contains Ibuprofen 100 mg

**Tablets:** Each tablet contains Ibuprofen 200 mg

Each tablet contains Ibuprofen 400 mg

### Pharmacological Actions

Ibuprofen has shown anti-inflammatory, antipyretic, and analgesic activity in both animals and humans. The exact mechanisms of action of the drug have not been clearly established, but many of the actions appear to be associated principally with the inhibition of prostaglandin synthesis. Ibuprofen inhibits synthesis of prostaglandins in body tissues by inhibiting cyclooxygenase; at least 2 isoenzymes, cyclooxygenase-1 (COX-1) and -2 (COX-2) (also referred to as prostaglandin G/H synthase-1 [PGHS-1] and -2 [PGHS-2], respectively), have been identified that catalyze the formation of prostaglandins in the arachidonic acid pathway. Ibuprofen, like other prototypical NSAIDs, inhibits both COX-1 and COX-2. Although the exact mechanisms have not been clearly established, NSAIDs appear to exert anti-inflammatory, analgesic, and antipyretic activity principally through inhibition of the COX-2 isoenzyme; COX-1 inhibition presumably is responsible for the drugs' unwanted effects on GI mucosa and platelet aggregation. Higher doses usually are required for anti-inflammatory effects than for analgesia. Ibuprofen inhibits platelet aggregation and prolongs bleeding time but does not affect prothrombin time or whole blood clotting time.

### Pharmacokinetics

Approximately 80% of an oral dose of ibuprofen is absorbed from the GI tract. Absorption rate is slower and plasma concentrations are reduced when ibuprofen tablets or suspension are taken with food; however, the extent of absorption is not affected.

The antipyretic effect of ibuprofen suspension begins within 1 hour after oral administration and peaks within 2-4 hours.

Approximately 90–99% of a dose is bound to plasma proteins. The plasma half-life of the drug has been reported to be 2–4 hours.

### Indication

Ibuprofen is used for anti-inflammatory and analgesic effects in the symptomatic treatment of rheumatoid arthritis, juvenile rheumatoid arthritis, and osteoarthritis.

Ibuprofen also is used to relieve mild to moderate pain and for the management of primary dysmenorrhoea. Ibuprofen has been used in the management of pericarditis. Ibuprofen also may be used for self-medication for analgesic effects to provide temporary relief of minor aches and pains, including those of arthritis, and of dysmenorrhea and for its antipyretic effect to reduce fever.

### Dosage and Administration

The usual adult dosage of ibuprofen in the symptomatic treatment of acute and chronic rheumatoid arthritis and osteoarthritis is 400–800 mg 3 or 4 times daily. Dosage should not exceed 3.2 g daily. The juvenile dosage is 30–40 mg/kg daily divided into 3 or 4 doses. For relief of mild to moderate pain, the usual adult dose is 400 mg every 4–6 hours as necessary. In children 6 months to 12 years of age, the recommended dose is 10 mg/kg every 6–8 hours. For the relief of primary dysmenorrhea, ibuprofen therapy should be started with the earliest onset of pain; the usual adult dosage in these patients is 400 mg every 4 hours as necessary for relief of pain.

For self-medication of fever, the usual initial adult dosage of ibuprofen is 200 mg every 4–6 hours; dosage may be increased to 400 mg.

For antipyresis in children 6 months to 12 years of age, the usual oral dosage of ibuprofen is 5 or 10 mg/kg for temperatures below or above 39°C, respectively.

### Contra-Indication

Safety and efficacy of ibuprofen in children younger than 6 months of age have not been established. Ibuprofen is contraindicated in patients with known hypersensitivity to the drug. NSAIDs, including

Ibuprofen, generally are contraindicated in patients in whom asthma, urticaria, or other sensitivity reactions are precipitated by aspirin or other NSAIDs. Although NSAIDs generally are contraindicated in these patients, the drugs have occasionally been used in NSAID-sensitive patients who have undergone desensitization.

NSAIDs are contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

### Precaution

The risk of potentially serious adverse GI effects should be considered in patients receiving ibuprofen, particularly in patients receiving chronic therapy with the drug. Since peptic ulceration and/or GI bleeding have been reported in patients receiving the drug, patients should be advised to promptly report signs or symptoms of GI ulceration or bleeding to their clinician.

Geriatric individuals appear to tolerate GI ulceration and bleeding less well than other individuals.

### Drug Interactions

Ibuprofen can antagonize the irreversible platelet-aggregation inhibition of aspirin and therefore may limit the cardioprotective effects of aspirin in patients with increased cardiovascular risk.

Ibuprofen has been reported to increase plasma or serum lithium concentrations by 12–67% and to reduce renal lithium clearance.

NSAIDs may reduce the natriuretic effect of furosemide or thiazide diuretics.

### Pregnancy and Lactation

Ibuprofen inhibits prostaglandin synthesis and release, which may cause dystocia, interfere with labor, and delay parturition. Inhibitors of prostaglandin synthesis may have adverse effects on the fetal cardiovascular system (e.g., premature closure of the ductus arteriosus).

Use of ibuprofen is not recommended during pregnancy (especially during the last trimester) or during labor and delivery.

Although ibuprofen has not been reported to distribute into milk in lactating women, the manufacturers state that use of the drug in nursing women is not recommended because of the potential risk of inhibitors of prostaglandin synthesis in neonates.

### Side Effects

Ibuprofen can cause gastric mucosal damage, which may result in ulceration and/or bleeding.

Hypersensitivity reactions manifested as a syndrome of abdominal pain, fever, chills, nausea, and vomiting have occasionally occurred during ibuprofen therapy. Anaphylaxis, anaphylactoid reactions, and bronchospasm have also occurred.

Although a causal relationship has not been established, serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis, and angioedema have also been reported during therapy with the drug. Other adverse effects of ibuprofen include dry mouth, gingival ulceration, and rhinitis. Although a causal relationship has not been established, gynecomastia, hypoglycemic reactions, and acidosis have also been reported during therapy with the drug.

### Storage:

Store in a dry place, below 30°C protected from light

Keep out of reach of children.

### Presentation:

Suspension in 60ml and 100ml amber bottle

Tablets, 200mg (1000's), 400mg (500's), Blister pack of 10 x 10 tablets

### Manufactured By:



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