



Advel®

Ibuprofen

Description: Advel® (Ibuprofen) is a propionic acid derivative. It has useful anti-inflammatory, analgesic and antipyretic activities. It has fewer side effects than other NSAIDs.

Mode of action: The analgesic and antipyretic effects of ibuprofen are the result of both peripheral and central effect. It is a potent inhibitor of the enzyme cyclooxygenase, which thus results in marked reduction in prostaglandin synthesis and in this way it shows its prominent anti-inflammatory action.

Pharmacokinetics: Following oral administration, ibuprofen is rapidly and almost completely absorbed. Peak serum level is achieved between 1 to 2 hrs after dosing and about 99% of ibuprofen is bound to plasma protein. Ibuprofen is extensively metabolized in the liver, with more than 90% of the dose excreted in the urine. Less than 10% is excreted unchanged and excretion is completed within 24 hours.

Composition: Advel® 200 mg Tablet: Each tablet contains 200 mg Ibuprofen BP.

Advel® 400 mg Tablet: Each tablet contains 400 mg Ibuprofen BP.

Advel® 100 ml Suspension: Each 5 ml suspension contains Ibuprofen BP 100 mg.

Indications: Advel® is indicated for the treatment of fever including post-immunization pyrexia and pain in children, pain and inflammation in rheumatic disease (including juvenile arthritis) and other musculoskeletal disorders, mild to moderate pain including dysmenorrhoea, postoperative analgesia & migraine.

Dosage & administration: Initial oral dosage is 200-400 mg 3-4 times daily preferably after food; increased upto 2.4 g if necessary.

The recommended dose for the treatment of Juvenile rheumatoid arthritis: Child over 7 kg body-weight 30-40 mg/kg daily in 3-4 divided doses. Fever and pain in children: Child over 7 kg body-weights: 20-30 mg/kg daily in divided doses, for 1-2 years: 50 mg, 3-4 times daily, 3-7 years: 100 mg 3-4 times daily, 8-12 years: 200 mg 3-4 times daily.

Contraindications: Ibuprofen should not be given to patients with known hypersensitivity to Ibuprofen or other NSAIDs, patients with history of peptic ulceration and to individuals who show bronchospastic reactivity to aspirin or other non-steroidal anti-inflammatory drugs.

Side effects: Usually ibuprofen has a low incidence of side effects. The most common side effects may include dyspepsia, headache, dizziness, nausea, vomiting, gastro-intestinal disturbance and skin rashes of various types. Less frequently, thrombocytopenia has occurred.

Use in pregnancy & lactation: Although no teratogenic effects have been demonstrated in animal experiments, the use of ibuprofen during pregnancy should, if possible be avoided. In the limited studies so far available, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the

breast-fed infant adversely.

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

Drug interactions: 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.

Over dosage: Symptoms of an Ibuprofen overdose include nausea, vomiting or stomach pain, dizziness, drowsiness, headache, ringing in the ears, blurred vision, seizures, sweating, numbness or tingling, little or no urine production, and slow breathing. Seek emergency medical attention if an overdose is suspected.

Storage: Store in a cool and dry place, protected from light.

Packaging

Advel® Tablet 200 mg: Each carton contains 10X10 tablets in blister pack.

Advel® Tablet 400 mg: Each carton contains 10X10 tablets in blister pack.

Advel® Suspension: Each bottle contains 100 ml suspension.

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