

Orcenac™

Aceclofenac

COMPOSITION:

Orcenac™ Tablet: Each film coated tablet contains Aceclofenac BP 100 mg.

Orcenac SR Tablet: Each sustained release tablet contains Aceclofenac BP 200 mg.

PHARMACOLOGY:

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. It is a potent inhibitor of the enzyme cyclooxygenase which is involved in the production of prostaglandin.

INDICATIONS:

Aceclofenac is indicated for the treatment of pain and inflammation in osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, low back pain and other acute musculoskeletal disorders like sprains, strains, dental and other minor surgery, postoperative pain, primary dysmenorrhoea etc.

DOSAGE AND ADMINISTRATION:

Route of Administration: Aceclofenac should be administered orally according to dosage guidelines.

Adult: 100 mg twice daily in the morning and in the evening or 200 mg once daily after meal. Reduce the doses to 100 mg once daily initially in patients with hepatic dysfunction.

Children: Not recommended.

CONTRAINDICATIONS:

Aceclofenac is contraindicated in the following situations such as:

- Patients previously sensitive to Aceclofenac or aspirin or other NSAIDs
- Patients with active suspected peptic ulcer or who have GI or other bleeding disorders
- In severe heart failure, renal or hepatic insufficiency
- During pregnancy and lactation

WARNINGS & PRECAUTIONS:

Aceclofenac should be used with caution in patients suffering from GI diseases and history of peptic ulcer. Caution should be exercised in patients with mild to moderate renal, hepatic and cardiac function. Caution is also required in patients with diuretic treatment.

SIDE-EFFECTS:

Aceclofenac is generally well-tolerated.

Common side effects: In the initial stage of therapy gastrointestinal disorders, headache, nausea, vomiting, dyspepsia, abdominal pain, flatulence etc. may appear.

Rare side effects: Allergic reactions, heart failure, ulcer etc.

USE IN PREGNANCY & LACTATION:

Use in pregnancy: In pregnancy, **Orcenac™** and **Orcenac SR** tablet should be avoided.

During lactation: **Orcenac™** and **Orcenac SR** tablet should not be used in nursing mothers

DRUG INTERACTIONS:

Aceclofenac may increase nephrotoxicity with concomitant use with diuretics. Serum potassium should be monitored when used with potassium sparing diuretics. The activity of anticoagulant may be enhanced when used concomitantly with Aceclofenac.

OVERDOSE:

Overdose of Aceclofenac can cause drowsiness, heartburn, indigestion, nausea and vomiting.

STORAGE:

Protect from light exposure. Store in cool & dry place at a temperature not exceeding 30°C. Keep out of the reach of children.

PACKING:

Orcenac™ Tablet: Each box contains 50 tablets in blister strip.

Orcenac SR Tablet: Each box contains 50 tablets in blister strip.

Manufactured by:

Organic Health Care Ltd.

Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur, Bangladesh.

