Movex®

Aceclofenac BP

Description
Aceclofenac is a nonsteroidal anti-inflammatory agent that exhibits analgesic and anti-inflammatory actions.

Mode of action
It inhibits prostaglandin synthesis by inhibiting cyclo-oxygenase enzyme. It also stimulates cartilage (glycosaminoglycan) synthesis.

Pharmacokinetics
After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentration is reached approximately within 1.25 to 3 hours after administration. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma. The mean plasma elimination half-life is around 4 hours. Aceclofenac is highly protein bound (>99%). 4-hydroxy-aceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

Composition
Movex® 100 mg Tablet: Each film-coated tablet contains Aceclofenac BP 100 mg.
Movex® SR 200 mg Tablet: Each sustained release tablet contains Aceclofenac BP 200 mg.

Indications
Aceclofenac is indicated for the relief of pain and inflammation associated with osteoarthritis, rheumatoid arthritis, ankylosing spondylitis.

Dosage & administration
Movex® 100 mg Tablet: *Adult (20 - 60 years):* The recommended starting dose 100 mg twice daily, one tablet in the morning and evening.
Movex® SR 200 mg Tablet: 200 mg once daily, one tablet in the morning or evening.
Child (4 - 12 years): There is no established data found about children use.
Renal impairment: No dose adjustment is required for mild to moderate kidney impairment patients.
Hepatic impairment: Dose should be reduce for hepatic impairment patients. started with 100 mg preferable.

Contraindications
Aceclofenac is contraindicated in patients previously sensitive to aceclofenac or aspirin or other NSAIDs. It should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding and moderate to severe renal impairment.

Side effects
Generally aceclofenac is well tolerated. The majority of side effects are reversible and mild which include gastrointestinal disorders (dyspepsia, abdominal pain, nausea and diarrhoea) and occasional occurrence of headache, dizziness or tiredness. Dermatological complaints including rash or itching, pruritus, abnormal hepatic enzyme levels and raised serum creatinine have occasionally been reported.

Use in pregnancy & lactation
USFDA pregnancy category C. There is no established data regarding uses in lactating mother. It should not be used in pregnancy & lactation until emergency.

Precautions
Aceclofenac should be administered with caution to patients with symptoms indicative of gastrointestinal disorders, with a history of peptic ulceration, ulcerative colitis, crohn's disease, hepatic porphyria, and coagulation disorders. Patients suffering from severe hepatic impairment must be monitored.

Drug interactions
Aceclofenac may inhibit the activity of diuretics. Anticoagulants: Like other NSAIDs, aceclofenac may enhance the activity of anticoagulants. Aceclofenac, like other NSAIDs, may increase plasma concentrations of lithium and digoxin. Concomitant therapy with aspirin, other NSAIDs and steroids may increase the frequency of side effects.

Over dosage
There is no human data available on the consequences of aceclofenac overdosage. After overdosage, following therapeutic measures to be taken. Absorption should be prevented as soon as possible by means of gastric lavage and treatment with activated charcoal. Supportive and symptomatic treatment should be given for complications.

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

Packaging
Movex® 100 mg Tablet: Each carton contains 10X10 tablets in blister pack.
Movex® SR 200 mg Tablet: Each carton contains 10X3 tablets in blister pack.

Opsonin Pharma
Ideas for healthcare

Manufactured by
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