ACECLO-P

Paracetamol & Aceclofenac Tablets 325 mg + 100 mg

Composition:
Each Uncoated Tablet Contains:
Paracetamol BP.....325mg
Aceclofenac BP.....100mg
Excipients.....q.s.

Pharmaceutical Form:
Uncoated Tablets.

Therapeutic indications:
ACECLO-P is indicated for the treatment of;
- Oedema and swelling
- Joint pains and trauma
- Dental pain
- Post-operative pain
- Pelvic inflammatory disease
- Deep Episiotomy
- Caesearian cases

Posology and method of administration:
Posology:
The recommended dose of ACECLO-P is, one tablet in morning and one tablet in evening preferably with or after food for the management of acute painful condition.
Or as directed by the physician.

Method of administration:
For oral administration.

Contraindications:
ACECLO-P is contraindicated in the following situations:
- Patients sensitive to Aceclofenac, Paracetamol or to any of the excipients of the formulation.
- Patients in whom aspirin or other NSAIDs, precipitate attacks of bronchospasm, acute rhinitis or urticaria or patients hypersensitive to these drugs.
- Patients with active or suspected peptic ulcer or gastrointestinal bleeding or bleeding disorders.
- Patients with severe heart failure, hypertension, hepatic or renal insufficiency.
- Third trimester of pregnancy.

Warnings and Precautions:
Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders, with a history suggestive of gastrointestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
Where gastrointestinal bleeding or ulceration occurs in patients receiving aceclofenac, the drug should be withdrawn.
Close medical surveillance is also imperative in patients suffering from severe impairment of hepatic function.
Aceclofenac should be given with caution to elderly patients with renal, hepatic or cardiovascular impairment and to those receiving other medication. The lowest effective dose should be used and renal function monitored regularly.
As with other NSAIDs, allergic reactions, including anaphylactic/ anaphylactoid reactions, can also occur without earlier exposure to the drug.
The importance of prostaglandins in maintaining renal blood flow should be taken into account in patients with impaired cardiac or renal function, those being treated with diuretics or recovering from major surgery. Effects on renal function are usually reversible on withdrawal of aceclofenac.
Caution should also be exercised in patients with history of coagulation defects and history of liver dysfunction.
Renal and hepatic function and blood counts should be monitored during long term treatment. Persistently elevated hepatic enzyme levels necessitate withdrawal of aceclofenac.
Chronic heavy alcohol abusers may be at increased risk of liver toxicity from excessive paracetamol use.
Renal impairment: Patients with mild renal impairment should be kept under surveillance since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly.
Hepatic impairment: The recommended initial dose of ACECLO-P should be reduced to one tablet daily in patients with impaired hepatic function.

Drug interactions:
Drug interactions associated with ACECLO-P are similar to those observed with other NSAIDs. Aceclofenac may increase plasma concentrations of lithium, digoxin and methotrexate, increase the activity of anticoagulants, inhibit the activity of diuretics, enhance cyclosporin nephrotoxicity and precipitate convulsions when co-administered with quinolone antibiotics. When concomitant administration with potassium sparing diuretics is employed, serum potassium should be monitored.
Furthermore, hypo or hyperglycemia may result from the concomitant administration of aceclofenac and antidiabetic drugs, although this is rare. The co-administration of aceclofenac with other NSAIDs or corticosteroids may result in increased frequency of side effects.
Potential hepatotoxicity of Paracetamol may be increased by large doses or long-term administration of barbiturates, carbamazepine, hydantoins, isoniazid, rifampin and sulfinpyrazone.

Pregnancy and Lactation:
ACECLO-P is a fixed combination of active ingredients including aceclofenac; it should not be used during pregnancy and lactation.

Undesirable effects:
Most of the adverse events are minor and reversible with treatment discontinuation.
Effects on gastrointestinal system: dyspepsia, abdominal pain and rise in hepatic enzymes.
Effects on skin: As with other NSAIDs, severe mucocutaneous skin reactions may also occur.
Other reactions: Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, demmtitis, headache, fatigue, allergic reactions, anemia, granulocytopenia, thrombocytopenia, neutropenia, oedema, palpitation, leg cramps, flushing, purpura, paraesthesia, tremors, gastrointestinal bleeding, gastrointestinal ulceration, pancreatitis, interstitial nephritis, depression, abnormal dreaming, somnolence, insomnia, vasculitis, hypoglycemia, rise in blood urea, serum creatinine and serum potassium.

Overdose:
Overdosage may cause nausea, vomiting, pain abdomen, dizziness, somnolence, headache, sweating, pancreatitis, hepatic failure and acute renal failure.

Treatment:
Includes gastric lavage, activated charcoal and other symptomatic measures as per medical advice.

Storage:
Store below 30°C in dry place, protect from light.
Keep the medicines out of the reach of children.

Presentation:
10 tablets in a blister pack.
Such 1 blister is packed in a printed carton along with pack insert.
Such 10 cartons are packed in one outer carton.

Manufactured by :

US Pharma®
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