

(Aceclofenac, Paracetamol Uncoated Bilayered Tablets)

Composition:

Each Uncoated Tablet Contains:

Aceclofenac.......... 100 mg
Paracetamol......... 325mg
Exicipents........... q.s.

Clinical Pharmacology:

Aceclofenac:

Aceclofenac works by inhibiting the action of cyclooxygenase (COX) that is involved in the production of prostaglandins (PG) which is accountable for pain, swelling, inflammation and fever.

Paracetamol:

Paracetamol has a central analgesic effect that is mediated through activation of descending serotonergic pathways. Debate exists about its primary site of action, which may be inhibition of prostaglandin (PG) synthesis or through an active metabolite influencing cannabinoid receptors.

Indications:

Indicated in Pain, Fever, Inflammation, anti-rheumatic, anti-inflammatory (both acute and chronic), analgesic (effective pain killer in lower backache, dental or gynecological pain) and antipyretic.

Contraindications:

Contraindicated in patients hypersensitive to aceclofenac or paracetamol other NSAIDs, or patients with a history of aspirin or NSAID related allergic or anaphylactic reactions or with peptic ulcers or GI bleeding, moderate or severe renal impairment.

Precautions and Warnings:

Allergies- Avoid if you have a known allergy to Aceclofenac or other NSAIDs.

Asthma- NSAIDs is not recommended if patient have been diagnosed with asthma.

Bleeding - NSAIDs is not recommended if patient has any bleeding disorder. It may cause

severe swelling and bleed in the stomach, colon, and anus.

Pregnancy- This medicine is not recommended in pregnant women.

Drug Interactions:

Drug interactions associated with aceclofenac 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 cyclosporine 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 hyperglycaemia may result from the concomitant administration of aceclofenac and antidiabetic drugs, although this is rare. The coadministration of aceclofenac with other NSAIDs or corticosteroids may result in increased frequency of side effects. Caution should be exercised if NSAIDs and methotrexate are administered within 2-4 hours of each other, since NSAIDs may increase methotrexate plasma

levels, resulting in increased toxicity.

Adverse effects:

The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, nausea, vomiting, diarrhea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, oedema, hypertension and cardiac failure have been reported in association

with NSAID treatment.

Overdosage:

Management of acute poisoning with NSAIDs essentially consists of supportive and

symptomatic measures.

For Therapeutic Use.

Route of administration: Oral.

Type of tablet: Uncoated Bilayered tablet.

Dosage: As directed by the physician.

Storage:

Store in cool, dry & dark place.

SCHEDULE H PRESCRIPTION DRUG-CAUTION: Not to be sold retail without the prescription of a Registered Medical Practitioner.

Presentation:

Ankinac-P Bilayered tablet is available as 10 x 10 Tablets.

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

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