

CePa-AL

(Aceclofenac and paracetamol Tablet)

Each Tablet Contains:

Aceclofenac IP100 mg
Paracetamol IP.....325 mg
Excipients.....q.s.

Clinical Pharmacology:

Aceclofenac: Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic, and antipyretic properties. Prostaglandins are chemical mediators involved in inflammation, pain, and fever. It is non-selective COX enzymes inhibitor which results in the inhibition of prostaglandin synthesis.

Paracetamol (Acetaminophen): Paracetamol is an analgesic and antipyretic. It works by inhibiting prostaglandin synthesis in the central nervous system and has a peripheral action by blocking pain-impulse generation. Unlike NSAIDs, paracetamol does not have significant anti-inflammatory effects.

Indications:

Relief of pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and musculoskeletal disorders

Relief of fever and mild to moderate pain of various origins (e.g., headaches, toothaches, backaches, postoperative pain)

Contraindications:

- Hypersensitivity to aceclofenac, paracetamol, or any other component of the tablet
- Severe hepatic or renal impairment
- History of gastrointestinal bleeding or perforation related to NSAID therapy
- Active peptic ulcer or history of recurrent peptic ulceration
- Use in patients with severe heart failure

Precautions and Warnings:

- **Gastrointestinal Risk:** NSAIDs, including aceclofenac, may increase the risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation.
- **Hepatic Effects:** Paracetamol in high doses or prolonged use may cause liver toxicity. Patients should be monitored for liver function.
- **Renal Impairment:** Long-term use of NSAIDs may lead to renal impairment. Caution is advised in patients with renal insufficiency.
- **Cardiovascular Risk:** NSAIDs may increase the risk of cardiovascular thrombotic events, myocardial infarction, and stroke.
- **Hypersensitivity Reactions:** Serious skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported in rare cases.

Drug Interactions:

- **Warfarin and Anticoagulants:** Paracetamol may increase the risk of bleeding when used with anticoagulants like warfarin.
- **Other NSAIDs and Corticosteroids:** Increased risk of gastrointestinal bleeding.
- **Diuretics and Antihypertensive Agents:** The efficacy of diuretics may be reduced by NSAIDs, and the risk of nephrotoxicity is increased when used together.
- **Alcohol:** Concurrent use of alcohol and paracetamol increases the risk of hepatotoxicity.

Adverse Effects:

Aceclofenac: Common adverse effects include gastrointestinal disturbances (nausea, dyspepsia, diarrhoea, abdominal pain), dizziness, and skin rash. Serious but rare effects include gastrointestinal bleeding, hypertension, and renal dysfunction.

Paracetamol: Paracetamol is generally well tolerated. Common adverse effects include nausea, vomiting, and allergic reactions such as rash. Rarely, hepatotoxicity or nephrotoxicity may occur with prolonged use or overdose.

Overdosage:

Aceclofenac: Symptoms of overdose may include nausea, vomiting, epigastric pain, gastrointestinal bleeding, headache, dizziness, and confusion. Supportive care and symptomatic treatment should be provided.

Paracetamol: Overdose can cause severe liver damage. Symptoms of overdose include nausea, vomiting, abdominal pain, and liver failure. Immediate medical attention and the use of an antidote (N-acetylcystiene) are critical in the case of overdose.

Route of Administration:

Tablet should be swallowed whole with sufficient amount of water. Do not crush or chew the tablet.

SCHEDULE H PRESCRIPTION DRUG CAUTION:

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Dosage: As directed by a physician. The typical adult dose is one tablet taken once or twice daily, depending on the severity of the condition.

Storage: Store in a cool, dry place below 25°C. Protect from light and moisture. Keep out of reach of children.

Presentation: Available as a strip of 10X10 tablets per pack.



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