



(Aceclofenac & Rabeprazole Capsules)

Composition:

Each capsule Contains:

Aceclofenac IP 200 mg

(as sustained release pellets)

Rabeprazole Sodium IP 20 mg

(as enteric coated pellets)

Colour: Red Oxide of Iron & Titanium Dioxide IP

Approved colours used in capsule shells.

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.

Rabeprazole

Rabeprazole belongs to a class of antisecretory compounds that suppress gastric acid secretion by inhibiting the gastric H⁺, K⁺ ATPase enzyme at the secretory surface of the gastric parietal cell. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, rabeprazole has been characterized as a gastric proton pump inhibitor. Rabeprazole blocks the final step of gastric acid secretion.

Indications:

- Painful rheumatic conditions like osteoarthritis.
- Rheumatoid arthritis.
- Ankylosing spondylitis.
- Minimise the gastric acid content caused by aceclofenac.

- Lowers the risk of ulcers.
- Heartburn.
- Acidity associated with painkillers.

Contraindications:

- Patients with a history of hypersensitivity to rabeprazole
- Proton pump inhibitors, including rabeprazole delayed-release tablets, are contraindicated in patients receiving rilpivirine-containing products
- Contraindicated in patients hypersensitive to aceclofenac or 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:

- Gastric Malignancy: In adults, symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing
- Acute Interstitial Nephritis: Observed in patients taking proton pump inhibitors
- Bone Fracture: Long-term and multiple daily dose proton pump inhibitors therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine.
- Pregnancy- This medicine is not recommended in pregnant women.
- 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.

Drug Interactions:

- Decreased exposure of some antiretroviral drugs (e.g., rilpivirine, atazanavir, and nelfinavir) when used concomitantly with rabeprazole may reduce antiviral effect and promote the development of drug resistance. Increased exposure of other antiretroviral drugs (e.g., saquinavir) when used concomitantly with rabeprazole may increase toxicity.
- 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.

Adverse effects:

- Most common adverse reactions in adults are pain, pharyngitis, flatulence, infection, and constipation, peptic ulcer, perforation or GI bleeding, hypertensive and cardiac failure.
- Most common adverse reactions in adolescents are headache, diarrhea, nausea, vomiting, and abdominal pain.

Overdosage:

There are no clinical signs or symptoms associated with any reported overdose.

For Therapeutic Use.

Route of administration: Oral.

Type of Capsule: Sustained release & Enteric coated pellets capsule.

Dosage: As Directed by the Physician.

Storage: Store protected from light & moisture, at a temperature not exceeding 30⁰ C.

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

Capsule should be swallowed whole not to be opened, chewed or crushed.

Presentation: Ankinac-RB capsule is available as 10 x 10 Capsule.

Marketed By:



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