

ACECLOFENAC**CLANZA****100 mg TABLET****Non-steroidal Anti-inflammatory Drug**

Manufactured by:

KOREA UNITED PHARM. INC.25-23, Nojanggongdan-gil, Jeondong-myeon,
Sejong-si, Korea

Imported & distributed by the Marketing Authorization Holder (MAH):

ONE PHARMA MARKETING INC.L51 B21 Abel Nosce St., BF Resort Village,
Talon II, Las Piñas City, Metro Manila**FORMULATION**

Each tablet contains

Aceclofenac.....100 mg

PHARMACODYNAMICS

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins.

PHARMACOKINETICS

Aceclofenac is well-absorbed from the gastro-intestinal tract; peak plasma concentrations are reached 1 to 3 hours after an oral dose. Aceclofenac is more than 99% bound to plasma proteins. The plasma-elimination half-life is approximately 4 hours. About two-thirds of a dose is excreted in the urine, mainly as hydroxymetabolites.

DESCRIPTION

White, round, biconvex film-coated tablet, engraved with "A" on one side, "UT" on the other side.

INDICATIONS

Aceclofenac is indicated for the relief of pain and inflammation in toothache, trauma, lumbago, osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

DOSAGE & ADMINISTRATION

Adults: The recommended dose is 200 mg daily, taken as two separate doses (every 12 hours). Or as prescribed by the physician.

Absolute contraindications:

Not to be given to those patients who have history of:

- Stroke: cerebrovascular accident, CVA
- Heart attack: Myocardial infarction, MI
- Coronary artery bypass graft, CABG
- Uncontrolled hypertension
- Congestive heart failure (CHF) NYHA II-IV

CONTRAINDICATIONS

Patients with allergy to these drugs or other analogues (diclofenac)
Patients with asthma. Non-steroidal anti-inflammatory drugs, acetylsalicylic acid and other drugs which inhibit prostaglandin-synthesis may precipitate attacks of asthma, acute rhinitis or urticaria.
Patients with active peptic ulcer.

ADVERSE EFFECTS

The majority of adverse-effects observed have been reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea), rash, urticaria, symptoms of enuresis, headache, dizziness and drowsiness.

WARNINGS

Close medical surveillance is imperative when the person who drinks alcohol regularly should take this drug or other antipyretics and analgesics. This drug may cause gastric-bleeding to this person.

PRECAUTIONS

Patients with symptoms of gastro-intestinal disorders and with a history of gastric ulcer.
Patients with moderate to severe hepatic impairment or cardiac or renal impairment. Dose adjustment and monitoring of liver and renal functions should be instituted.
Patients under the medication of diuretics.
Patients in recovery after surgical treatment.
The elderly.
Patients suffering from dizziness, vertigo, or other central nervous system disorders while taking NSAIDs (Non-steroidal anti-inflammatory drugs) should refrain from driving or handling dangerous machinery.

DRUG INTERACTIONS

There has been no drug interactions reported, but close monitoring of patients on combination with lithium and digoxin, oral antidiabetic agents, anticoagulants, diuretics, and other analgesics.

USE IN PREGNANCY AND CHILDREN

Since there is no information on the safe use of aceclofenac during pregnancy and lactation, the use of aceclofenac should be avoided in pregnancy and lactation.
The dosage and indication is not yet established for children less than 6 years old.

OVERDOSAGE

There are no human data available on the consequences of aceclofenac overdosage. If overdosage is observed, therapeutic measures should be taken according to symptoms; supportive and symptomatic treatment should be given for complications such as hypotension, gastro-intestinal irritation, respiratory depression, and convulsions.

STORAGE

Store at temperatures not exceeding 30°C.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY

In Alu/PVC Blister Pack x 10's (Box of 100's)

Keep out of reach of children.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph