Panacea Biotec
Innovation in support of life

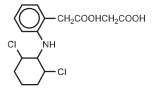
For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Aceclofenac Controlled Release Tablets 200 mg

Willgo CR

COMPOSITION
Each film coated controlled-release tablet contains:
Aceclofenac Ph. Eur. 200 mg
(as controlled-release).
Colour: Ferric Oxide (Yellow).

DESCRIPTION
Aceclofenac is a white or almost white, crystalline powder that is practically insoluble in water, freely soluble in acetone and soluble in alcohol. Aceclofenac is a phenyl acetic acid derivative with a chemical designation of [2-{(2,6-dichlorophenyl)amino} phenylacetoxyacetic acid] and has the following structural formula



WILLGO CR tablet is available in 200 mg strength and are light yellow/ white coloured, oblong, biconvex, film-coated tablets engraved with ACR on one side and 200 on other side. Aceclofenac has a short half-life of approximately 3.5–6.2 hours, which necessitates dosing every 12 hours to maintain optimum levels of analgesia (1). Considering the long-term use of aceclofenac, once-daily (OD) controlled-release formulations are desirable for better pain control, enhanced clinical efficacy, and improved patient compliance. Thus, aceclofenac CR tablets was designed to give an initial release to provide the similar plasma concentration of the immediate release formulation for rapid onset, and the controlled release of aceclofenac over 24 hours.

INDICATIONS
WILLGO CR Tablets are indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, scapulohumeral periarthritis (frozen shoulder), lumbago, pain caused by nonaticular rheumatism, musculoskeletal sprains - strains, and relief of arthritis related pain and early morning stiffness.

DOSAGE AND ADMINISTRATION
The recommended dose of WILLGO CR 200 mg Tablet is once daily (every 24 hours) or as prescribed by the physician. It should be taken preferably with or after food at the same time every day.

USE IN SPECIAL POPULATION
Pregnancy and Lactation
Since there is no information on the safe use of Aceclofenac CR during pregnancy and lactation, the use of Aceclofenac CR should therefore be avoided in pregnancy and lactation.
Use in Children
The dosage and indication is not established in children less than 6 years of age.

CONTRA-INDICATIONS
- Patients with allergy to Aceclofenac or any of its components and other analogues (diclofenac).
- Patients with asthma, NSAIDS, acetylsalicylic acid and other drugs which inhibit prostagladin-synthesis may precipitate attacks of asthma, acute rhinitis or urticaria.
- Patients with active peptic ulcer.

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.

PRECAUTIONS
- Patients suffering from dizziness, vertigo, or other central nervous system disorders while taking NSAIDS should refrain from driving or handling dangerous machinery
- Patients with symptoms of gastrointestinal disorders and with a history of gastric ulcer.
- Patients with moderate to severe hepatic or cardiac or renal impairment.
- Patients under the medication of diuretics.
- Patient in recovery after surgical treatment.

DRUG INTERACTIONS
There has been no drug interactions reported, but close monitoring is required in patients taking Aceclofenac in combination with lithium and digoxin, oral antidiabetic agents, anticoagulants, diuretics, and other analgesics.

UNDESIRABLE EFFECTS
The majority of side effects observed have been reversible and of a minor nature and include gastrointestinal disorders (dyspepsia, abdominal pain, nausea), rash, redness urticaria, symptoms of enuresis, headache, dizziness, and drowsiness.

OVERDOSAGE
There are no human data available on the consequences of Aceclofenac CR 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.

CLINICAL PHARMACOLOGY
Aceclofenac, a non-steroidal anti-inflammatory drug (NSAID), is effective in the treatment of various kinds of pain, inflammation, rheumatoid arthritis and osteoarthritis. The inhibitory effects of aceclofenac on synovial levels of prostaglandin E2 have been confirmed in patients with acute knee pain and synovial effusions. In addition, it has been reported that aceclofenac has a reduced side-effect profile, especially with regard to gastrointestinal events, which are experienced frequently with NSAID therapy. Thus, aceclofenac has been used to treat more than 75 million patients worldwide (1).
In 4 weeks of clinical trial involving patients with chronic knee OA confirms aceclofenac CR 200 mg formulation was equivalent to aceclofenac IR 100 mg formulation with respect to pain relief and safety among patients with chronic OA of the knee (2). In addition, the once daily dosage of aceclofenac CR contributed to enhanced patient compliance (2).
A bioavailability study reported in literature has shown that aceclofenac CR 200 administered OD is equivalent to conventional immediate-release aceclofenac100 mg administered BID with respect to the AUC_{24} and C_{max} of aceclofenac in healthy subjects. Also, concomitant intake of high-fat food does not affect the pharmacokinetics of controlled-release aceclofenac. This enhances its ease of use by the patient (1).

PHARMACODYNAMIC / PHARMACOKINETIC ACTIONS
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 of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins.

Pharmacokinetics
After oral administration, aceclofenac is rapidly and completely absorbed as unchanged drug. Peak plasma concentrations (C_{max}) of 11416.94 ng/mL are reached approximately 2.11 ± 0.89 hours following ingestion of single dose of 200 mg aceclofenac CR tablet. Aceclofenac penetrates into the synovial fluid, where the concentrations reach approximately 57% of those in plasma.
The mean plasma elimination half-life is around 3.56 hours. Aceclofenac is highly protein- bound (>99%). Aceclofenac circulates mainly as unchanged drug. 4'- hydroxyaceclofenac is the main metabolite detected in plasma. Approximately two-thirds of the administered dose is excreted via the urine, mainly as hydroxymetabolites.

LIST OF EXCIPIENTS
Lactose, Microcrystalline cellulose, low substituted hydroxypropyl cellulose, colloidal silicon dioxide, Purified Talc, Magenesium stearate, hydroxypropylmethylcellulose, stearic acid, Ferric oxide(yellow), methylene chloride, isopropyl alcohol

SHELF-LIFE
Do not use the product after Expiry Date indicated on Carton.

PACKAGING INFORMATION
Blister Pack of 10 tablets.

STORAGE AND HANDLING INSTRUCTIONS
Store below 30°C, protect from light and moisture.
KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

REFERENCES:

1. Bae SK, Kim SH, Lee HW, et al. Pharmacokinetics of a new once-daily controlled-release formulation of aceclofenac in Korean healthy subjects compared with immediate-release aceclofenac and the effect of food. Clin Drug Investig 2012; 32 (2): 111-119.
2. Moon YW, Kang SB, Kim TK, et al. Efficacy and safety of aceclofenac controlled release in patients with knee osteoarthritis: a 4-week, multicenter, randomized, comparative clinical study. Knee Surg Relat Res 2014;26(1):33-42.

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PPIW011A

Product Name	**Willgo CR**	**Change Control No.: BCC103/19**
Item Code	PPIW011A	**Colours: Black**
Size	120x160 mm	
Market	Domestic	**Revision No:** 00