SUMMARY OF PRODUCT CHARACTERISTICS

WILLGO CR

(Aceclofenac Controlled-Release Tablets 200mg)

1. NAME OF THE MEDICINAL PRODUCT

Aceclofenac Controlled Release 200 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Film coated tablet contains;

Aceclofenac Ph. Eur.…200mg

(as controlled-release)

Colour-: Ferric Oxide (Yellow)

3. PHARMACEUTICAL FORM

Tablets oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

WILLGO CR is indicated for relief of pain and inflammation in rheumatoid arthritis, ankylosing spondilytis, osteoarthritis and periarthritis of s capulohumerous, lumbago, ischiadynia, pain caused by nonaticular rheutism, muscoskeletal sprains- strains, and relief of arthritis related pain and early morning stiffness.

4.2 Posology and Method of Administration:

Adults: The recommended dose is 200 mg daily, taken as one dose (every 24 hours), or as prescribed by the physician.

Use in Children

The dosage and indication is not established in children less than 6 years of age.

4.3 Contraindications

- Patients with allergy to these drugs or 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.

4.4 Special Warnings and Special Precautions for Use.

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 gastro –intestinal 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.

4.5 Interaction with Other Medicaments and Other Forms of Interaction

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.

4.6 Pregnancy, Lactation and Fertility

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.

4.7 Effects on Ability to Drive and Use Machines

Undesirable effects such as dizziness, vertigo, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 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.

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

ATC Code: M01AB16

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.

5.2 Pharmacokinetic Properties

After oral administration, mean peak plasma concentrations achieved at 2.11 ± 0.89 hr following ingestion. Tlast was 16.00 to 20.00 hr and drug was available for prolonged time.The mean plasma elimination half-life is around 3.56 hours. The volume of distribution was 13.77 ± 4.72L.

5.3 Preclinical safety data

The results from preclinical studies conducted with acec lofenac are consistent with those expected for NSAIDs. The principal target organ was the gastro-intestinal tract. No unexpected findings were recorded.

Aceclofenac was not considered to have any mutagenic activity in three in vitro studies and an in vivo study in the mouse.

Aceclofenac was not found to be carcinogenic in either the mouse or rat.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients: Lactose Monohydrate, Cellulose Microcrystalline, Ferric Oxide (Yellow), Low su bstituted hy droxypropyl Cellulose, Anhydrous Collo idal S ilica, T alc, Magnesium Stearate, Hy promellose (2 208) (K4MCR), St earic acid, o padry Clear (21K590009), Methylene Chloride, Isopropyl alcohol.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 Months

6. 4 Storage Instructions

Store below 30°C, protection from light and moisture.

6.5 Nature and Contents of Container

5 x 2 x 10 Tablets (10 number of tablets are packed in push through blister strip and 2 number of such strips are packed in inner carton and 1 such carton is pack ed in outer carton along with package insert).

10 x 10 Tablets (10 number of tablets are packed in push through blister strip and 10 number of such strips are packed in a carton along with package insert).

6.6 Instructions for User Handling

Keep the medicine out of reach of children

7. Marketing Authorization Holder

Panacea Biotec Pharma Ltd.

B-1/A-27, Mohan Co-op.Indl. Estate,

Mathura Road, New Delhi – 110 044

INDIA

8. MARKETING AUTHORISATION NUMBER(S)

Not Applicable

9. DATE OF FIRST AUTHORISATION

Not Applicable

10. DATE OF TEXT PREPARATION

Not Applicable