CLANZA CR- aceclofenac tablet, film coated
United Douglas Pharm., Inc.

DESCRIPTION

White, oblong, film-coated tablet, engraved with "UT" on one side and "CL CR" on the other side.

INDICATIONS

CLANZA CR is indicated for Rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and periarthritis of scapulohumerous, lumbago, ischiadynia, pain caused by nonaticular rheutism.

Dosage and Administration

Adults: The recommended dose is 200 mg daily, taken as one dose (every 24 hours). However, the dose and dose frequency of CLANZA CR can be modified under the supervison of physician or pharmacist.

CONTRAINDICATIONS

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

CAUTIONS

Patients with symptoms indicative of gastro-intestinal disorders, with a history of gastroulceration. Patients with severe hepatic impairment or cardiac or renal impairment. Patients under the medication of diuretics. Patients in recovery after surgical treatment.

ADVERSE REACTIONS

The majority of side effects observed have been reversible and of a minor nature and include gastro-intestinal disorders (dyspepsia, abdominal pain, nausea), rash, ruber, urticaria, symptoms of enuresis, headache, dizziness, and drowsiness. To report suspected adverse reactions, call 1-800-FDA-1088.

GENERAL PRECAUTIONS

Patients suffering from dizziness, vertigo, or other central nervous system disorders while taking NSAIDS 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 NURSING MOTHERS

Since there is no information on the safe use of CLANZA CR during pregnancy and lactation, the use of CLANZA CR should therefore be avoided in pregnancy and lactation.

USE IN CHILDREN

The dosage and indication is not established yet for children with less than 6 years old.

OVERDOSAGE

There are no human data available on the consequences of CLANZA 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.

STORAGE

Preserve in tight containers. Store at room temperature not exceeding 30°C.

SHELF LIFE

Three (3) years from manufacturing date. ***Do not exceed the expiry date for use printed on the box.***

PACKAGE

10 Blister Packs with 10 Tablets in each Blister Pack

Enter section text here

label test

CLANZA CR

aceclofenac tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65697-450
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Aceclofenac (UNII: RPK779R03H) (Aceclofenac - UNII:RPK779R03H)	Aceclofenac	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Sodium Carbonate (UNII: 45P3261C7T)	
Colloidal Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Crospovidone (UNII: 68401960MK)	
Poloxamer 407 (UNII: TUF2IVW3M2)	

Magnesium Stearate (UNII: 70097M6I30)	
Alcohol (UNII: 3K9958V90M)	
Hypromellose 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
Carbomer 941 (UNII: F68VH75CJC)	
Hypromellose 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
Alcohol (UNII: 3K9958V90M)	
Methylene Chloride (UNII: 588X2YUY0A)	
Hypromellose 2910 (5 MPA.S) (UNII: R75537T0T4)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Ethylcelluloses (UNII: 7Z8S9VYZ4B)	
Diethyl Phthalate (UNII: UF064M00AF)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL (Film-coated white oblong tablet)	**Size**	15mm
Flavor		**Imprint Code**	UT;CR;CT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65697-450-20	1 in 1 PACKET		
2	NDC:65697-450-22	10 in 1 CARTON		
2	NDC:65697-450-21	10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/12/2011	

Labeler - United Douglas Pharm., Inc. (001444350)

Registrant - United Douglas Pharm., Inc. (001444350)

Establishment

Name	Address	ID/FEI	Business Operations
United Douglas Pharm., Inc.		001444350	pack, label

Establishment

Name	Address	ID/FEI	Business Operations
Korea United Pharm Inc.		688016534	manufacture

Revised: 11/2011 United Douglas Pharm., Inc.