

**DICLOFENAC SODIUM- declofenac sodium tablet, delayed release
DIRECT RX**

DICLOFENAC SODIUM D\R 75mg 30 CAPS

DESCRIPTION

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CLINICAL PHARMACOLOGY

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INDICATIONS AND USAGE

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CONTRAINDICATIONS

-

WARNINGS

-

PRECAUTIONS

-

ADVERSE REACTIONS

-

OVERDOSAGE

-

DOSAGE & ADMINISTRATION

-

MEDICATION GUIDE

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PRINCIPAL DISPLAY PANEL

D **DICLOFENAC SODIUM D/R**
75mg 30 Tabs

Generic For: **VOLTAREN**
Each enteric-coated tablet contains: Diclofenac Sodium USP 75mg (Delayed-Release)

Lot# Prod# 686-30 Discard After: 06/18

AF008
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert.Store between 68-77 degrees F

M
NDC 61919-686-30
May cause drowsiness or dizziness.

DICLOFENAC SODIUM D/R 75mg
NDC 61919-686-30 30 Tabs
Lot Exp Date 06/18
Nty NDC 16571-201-11

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Dist By: Park Pharm, LLC
Burling Grove, IL 60089
NDC 16571-201-11

Mfg Lot: 4172016

Packaged and Distributed By: **DIRECT**

Alpharetta, GA 30005

DICLOFENAC SODIUM

diclofenac sodium tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-686(NDC:16571-201)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:14408QL0L1)	DICLOFENAC SODIUM	75 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
WATER (UNII: 059QF0KO0R)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	brown (Light Brown)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	P;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-686-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077863	04/11/2016	

Labeler - DIRECT RX (079254320)**Establishment**

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-686)

Revised: 4/2016

DIRECT RX