

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

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**DICLOFENAC SODIUM DR 75mg 20 TABS**

**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 AND ADMINISTRATION**

- 

**MEDICATION GUIDE**

- 

**PACKAGE LABEL- 75 mg container label**

**D** **DICLOFENAC SODIUM D/R**  
**75mg 20 Tabs**

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

Lot# Prod# 686-20 Discard After: 03/17

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

Mfg Lot: 3/22/2016

Dir. By: Park Pharm., LLC  
Burlingame Drive, IL 60009  
NDC 16571-201-11

**M**

**May cause drowsiness or dizziness.**

**RX ONLY-KEEP OUT OF REACH OF CHILDREN**

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

Dosage: See package insert. Store between 68-77 degrees F.

DICLOFENAC SODIUM D/R 75mg  
NDC 61919-686-20 20 Tab  
Lot Exp Date 03/17  
Mfg NDC 16571-201-11

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AF LAB

NDC 61919-686-20

Revision Effective Date

## 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:144O8QL0L1)	DICLOFENAC SODIUM	75 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3W0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

### 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:61919-686-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077863	03/22/2016	

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

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

Revised: 4/2016

DIRECT RX