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

-

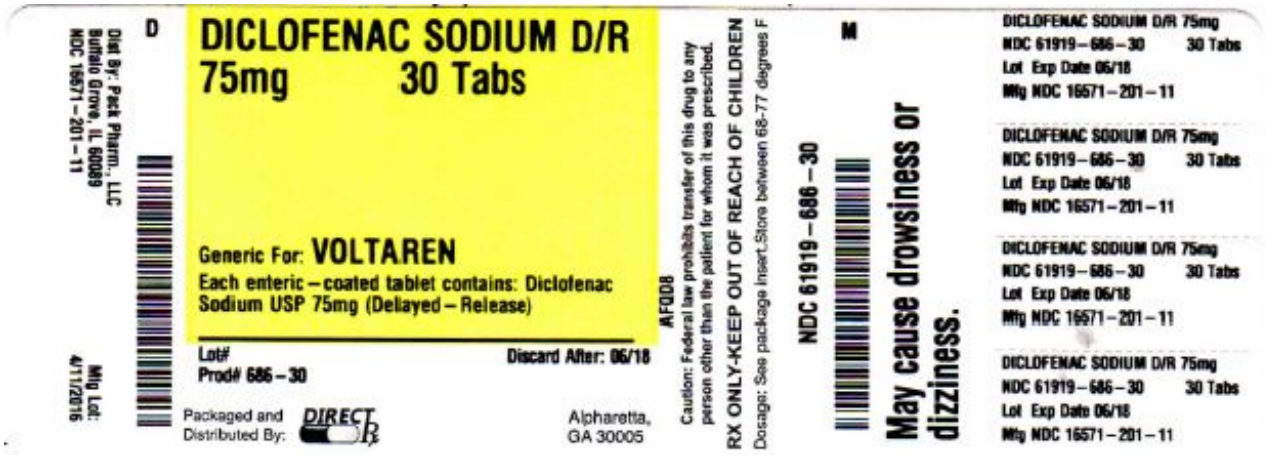
DOSAGE & ADMINISTRATION

-

MEDICATION GUIDE

-

PRINCIPAL DISPLAY PANEL



DICLOFENAC SODIUM

declofenac 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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
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