DICLOFENAC SODIUM- diclofenac sodium liquid
Zydus Lifesciences Limited

DICLOFENAC SODIUM TOPICAL SOLUTION

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

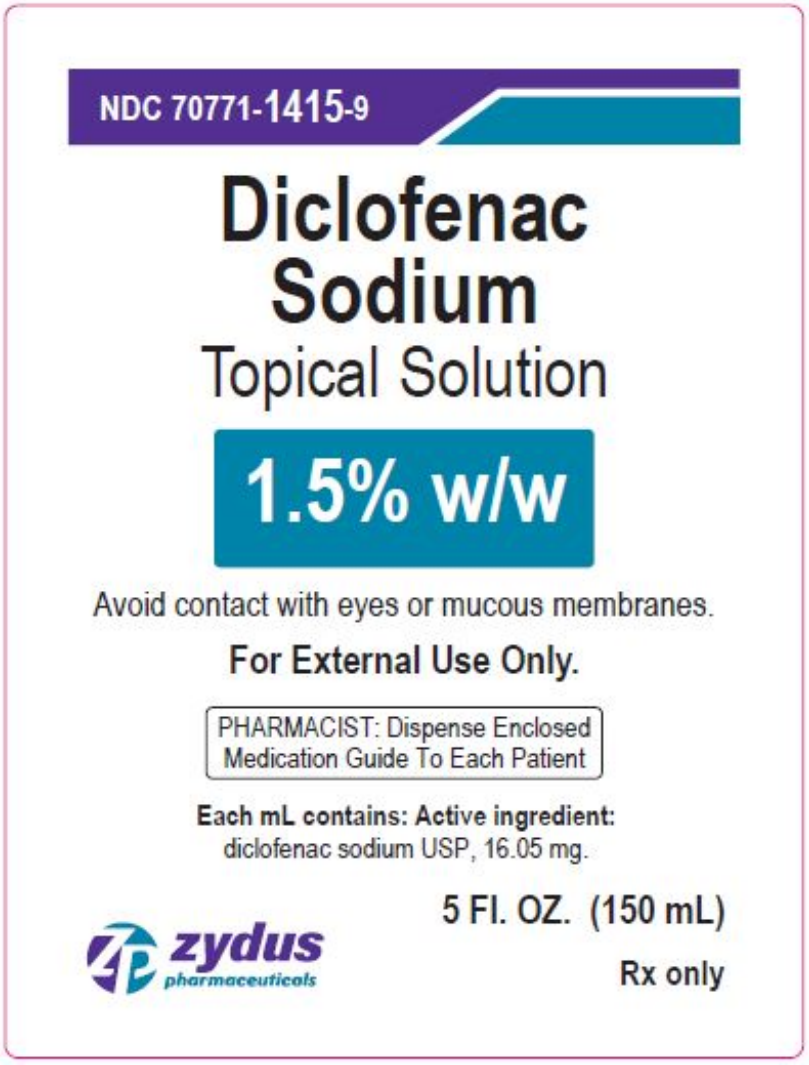
NDC 70771-1415-9

Diclofenac Sodium Topical Solution, 1.5% w/w

Rx only

Quantity 5 Fl. OZ.

(150 mL)



Usual dosage: 40 drops to a knee, 4 times a day. Apply diclofenac sodium topical solution to clean, dry skin. Allow several minutes for diclofenac sodium topical solution to dry.

Warning: If persistent skin irritation develops, discontinue use of product and consult your physician.

After application, wash the hands.

See package insert for complete prescribing information.

Excipients: alcohol USP 11.79% w/w (equivalent to 14.58% v/v absolute alcohol), dimethyl sulfoxide, glycerin, propylene glycol and purified water.

Storage: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) (see USP controlled room temperature).

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 08/18

Lot:

Exp:

DICLOFENAC SODIUM

diclofenac sodium liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1415
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	16.05 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1415-9	1 in 1 CARTON	08/08/2018	
1		150 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206411	08/08/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (650650802)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1415) , MANUFACTURE(70771-1415)

Revised: 10/2023 Zydus Lifesciences Limited