DICLOFENAC SODIUM- diclofenac sodium gel
Two Hip Consulting, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

INDICATIONS: For the topical treatmentof active keratosis.

INACTIVE INGREDIENTS

HYALURONATE SODIU, BENZYL ALCOHOL, POLYETHYLENE GLYCOL MONOMETHYL ETHER, PURIFIED WATER.

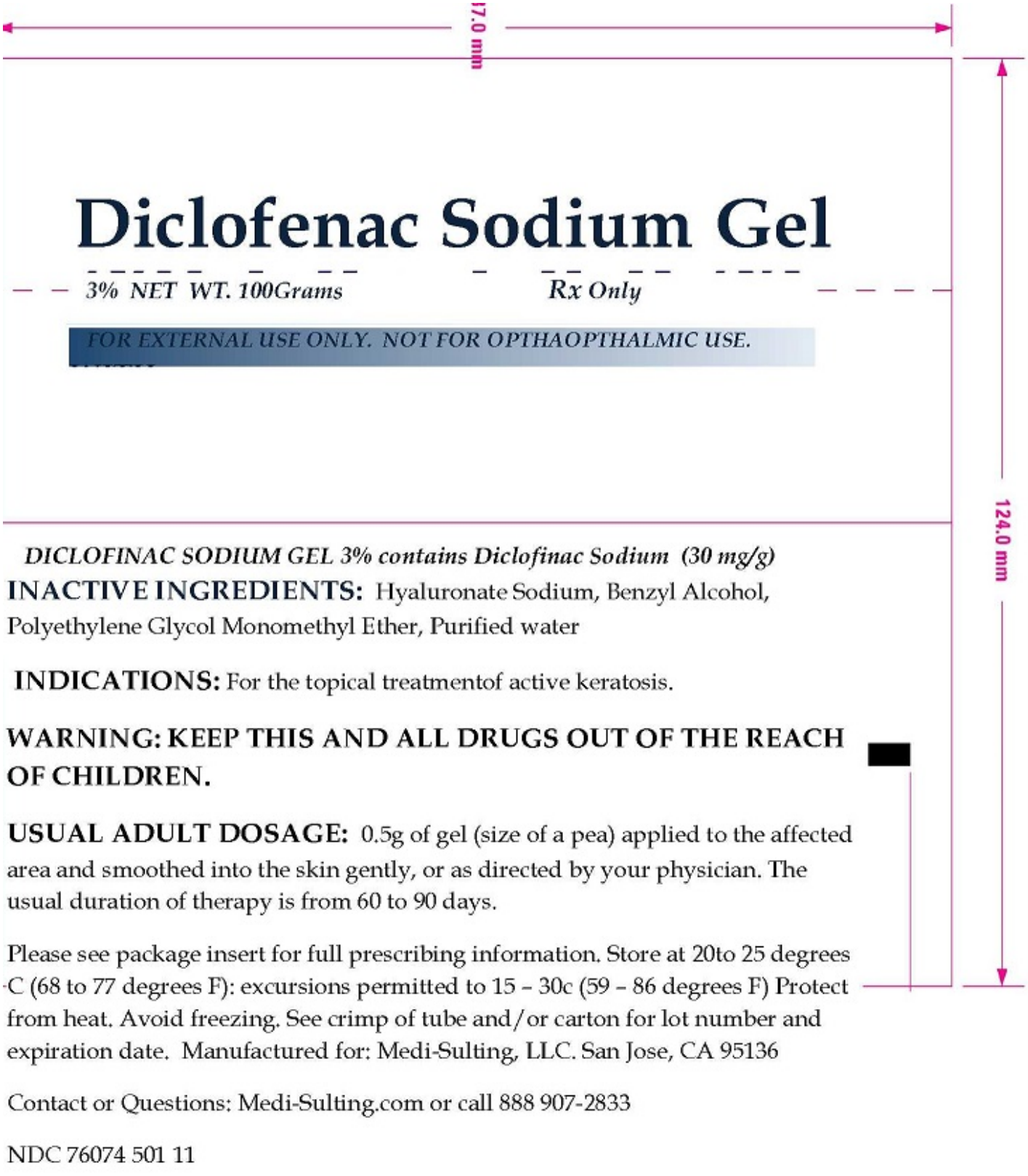
USUAL ADULT DOSAGE

0.5G OF GEL (SIZE OF A PEA APPLIED TO AFFECTED AREA AND SMOOTHED INTO SKIN GENTLY, OR AS DIRECTED BY YOUR PHYSICIAN. THE USUAL DURATION OF THERAPY IS FROM 60 TO 90 DAYS.

WARNING

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Please see package insert for full prescribing information. Store at 20 to 25 degrees C (68 to 77 degrees F): excursions permitted to 15 – 30 C (59 – 86 degrees F) Protect from heat. Avoid freezing. See crimp of tube and/or carton for lot number and expiration date.



Diclofenac Sodium Gel

3% NET WT. 100Grams *Rx Only*

FOR EXTERNAL USE ONLY. NOT FOR OPTHAOPTHALMIC USE.

DICLOFINAC SODIUM GEL 3% contains Diclofinac Sodium (30 mg/g)

INACTIVE INGREDIENTS: Hyaluronate Sodium, Benzyl Alcohol, Polyethylene Glycol Monomethyl Ether, Purified water

INDICATIONS: For the topical treatmentof active keratosis.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

USUAL ADULT DOSAGE: 0.5g of gel (size of a pea) applied to the affected area and smoothed into the skin gently, or as directed by your physician. The usual duration of therapy is from 60 to 90 days.

Please see package insert for full prescribing information. Store at 20to 25 degrees C (68 to 77 degrees F): excursions permitted to 15 – 30c (59 – 86 degrees F) Protect from heat. Avoid freezing. See crimp of tube and/or carton for lot number and expiration date. Manufactured for: Medi-Sulting, LLC. San Jose, CA 95136

Contact or Questions: Medi-Sulting.com or call 888 907-2833

NDC 76074 501 11

DICLOFENAC SODIUM

diclofenac sodium gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76074-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	3 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHOXY PEG-40 (UNII: 6AXS45P1QU)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76074-501-11	100 g in 1 TUBE; Type 0: Not a Combination Product	04/04/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/25/2016	

Labeler - Two Hip Consulting, LLC (965352896)

Registrant - Two Hip Consulting, LLC (965352896)

Revised: 2/2019 Two Hip Consulting, LLC