

**DICLOFENAC SODIUM- diclofenac sodium gel**  
**EXELAN PHARMACEUTICALS INC.**

-----  
**Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever**

**ACTIVE INGREDIENT**

Diclofenac sodium (NSAID\*) 1% (equivalent to 0.93% diclofenac)

\*nonsteroidal anti-inflammatory drug

**PURPOSE**

Arthritis pain reliever

**USES**

- for the temporary relief of arthritis pain ONLY in the following areas:
  - hand, wrist, elbow (upper body areas)
  - foot, ankle, knee (lower body areas)
- this product may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief in 7 days, stop use.

**WARNINGS**

**For external use only**

**Allergy alert:** Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver warning:** This product contains diclofenac. Liver damage may occur if you apply

- more or for a longer time than directed
- when using other drugs containing diclofenac

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- apply more or for longer than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

### **Do not use**

- if you have ever had an allergic reaction to any other pain reliever or to a fever reducer
- for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.
- right before or after heart surgery
- on more than 2 body areas at the same time
- in the eyes, nose or mouth

### **Ask a doctor before use if**

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you are under age 18 years. It is not known if this drug works or is safe in children under age 18 years.

### **Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking any other drug

### **When using this product**

- avoid contact with eyes, nose, or mouth
- if eye contact occurs, rinse thoroughly with water

### **Stop use and ask a doctor if**

- pain gets worse or lasts more than 21 days
- redness or swelling is present in the painful area
- fever occurs
- skin irritation occurs
- any new symptoms appear. These could be signs of a serious condition.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools

- vomit blood
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - leg swelling
  - weakness in one part or side of body
  - slurred speech

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**OTC - KEEP OUT OF REACH OF CHILDREN SECTION**

**Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.**

**DIRECTIONS**

Use up to 21 days unless directed by your doctor

Not for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.

<b>Daily</b>	<b>Per Dose</b>
<p><b>For your arthritis pain:</b></p> <ul style="list-style-type: none"> <li>• Use 4 times per day every day</li> <li>• Do not use on more than 2 body areas at the same time</li> </ul>	<p><b>Use ENCLOSED DOSING CARD to measure a dose</b></p> <ul style="list-style-type: none"> <li>• For each upper body area (hand, wrist, or elbow) - Squeeze out 2.25 inches (2 grams)</li> <li>• For each lower body area (foot, ankle or knee) - Squeeze out 4.5 inches (4 grams)</li> </ul>

**READ THE ENCLOSED USER GUIDE FOR COMPLETE INSTRUCTIONS**

- use only as directed
- do not use more than directed or for longer than directed
- apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes
- do not apply in same area as any other product

- do not apply with external heat such as heating pad
- do not apply a bandage over the treated area
- store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical gel, 1%. The dosing card is re-usable.
- store at 20°C to 25°C (68°F to 77°F). Keep from freezing.
- read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.

## INACTIVE INGREDIENTS

carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution

## QUESTIONS OR COMMENTS

**1-866-604-3268**

## SPL UNCLASSIFIED SECTION

### Additional Information

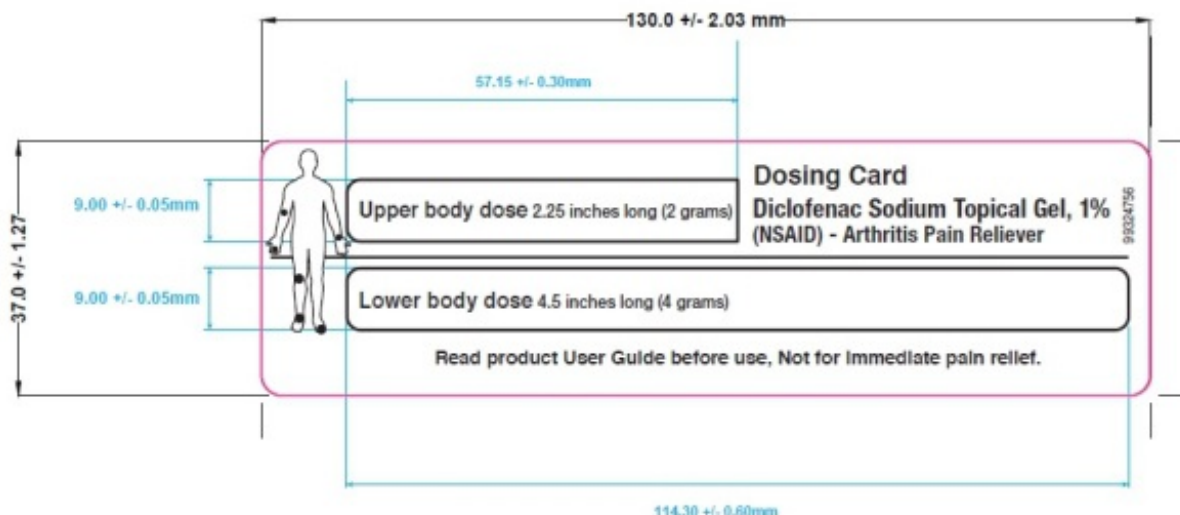
### ORIGINAL PRESCRIPTION STRENGTH

### Medicated Gel Clinically Proven to Relieve Arthritis Pain

### TREATMENT AREAS

- **Hand Wrist Elbow Foot Ankle Knee**
- Not for use on any other body area (such as back, hip, or shoulder)

## USE ENCLOSED DOSING CARD TO MEASURE A DOSE



## **Dosing Card**

### **Diclofenac Sodium Topical Gel, 1%**

(NSAID) - Arthritis Pain Reliever

Read product User Guide before use

Not for immediate pain relief

**Upper body dose** 2.25 inches long (2 grams)

**Lower body dose** 4.5 inches long (4 grams)

#### **HOW TO USE**

- For arthritis pain only
- Use 4 times a day
- May take up to 7 days to work for your arthritis pain
- For use on no more than 2 body areas
- Use up to 21 days unless directed by your doctor
- **Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.**

#### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**Cipla**

NDC 76282-103-39

Diclofenac Sodium Topical Gel, 1%

(NSAID) - Arthritis Pain Reliever

NET WT 100 g (3.53 oz)

NDC 76282-103-39

# Diclofenac Sodium Topical Gel

1%

(NSAID) - Arthritis Pain Reliever



NET WT 100 g (3.53 oz)

To open tube: Unscrew cap and press the spike on the top of the cap onto the seal on the tube.

This tube does not contain full product information.

Retain outer carton, dosing card, and User Guide for full product uses, directions and warnings.

Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.

### Warnings

#### For external use only

**Allergy alert:** Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Liver warning:** This product contains diclofenac. Liver damage may occur if you apply

- more or for a longer time than directed
- when using other drugs containing diclofenac

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug

- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- apply more or for longer than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### Keep out of reach of children.

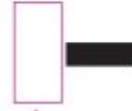
- store at 20°C to 25°C (68°F to 77°F). Keep from freezing.

Questions or comments? 1-866-604-3268

Manufactured by: DPT Laboratories, Ltd.  
307 E. Josephine Street San Antonio, TX 78215  
Manufactured for: Exelan Pharmaceuticals, Inc.  
Boca Raton, FL 33432

Rev. 02/2004

Lot and Exp. on crimp



## Cipla

NDC 76282-103-39

Diclofenac Sodium Topical Gel, 1%

(NSAID) - Arthritis Pain Reliever

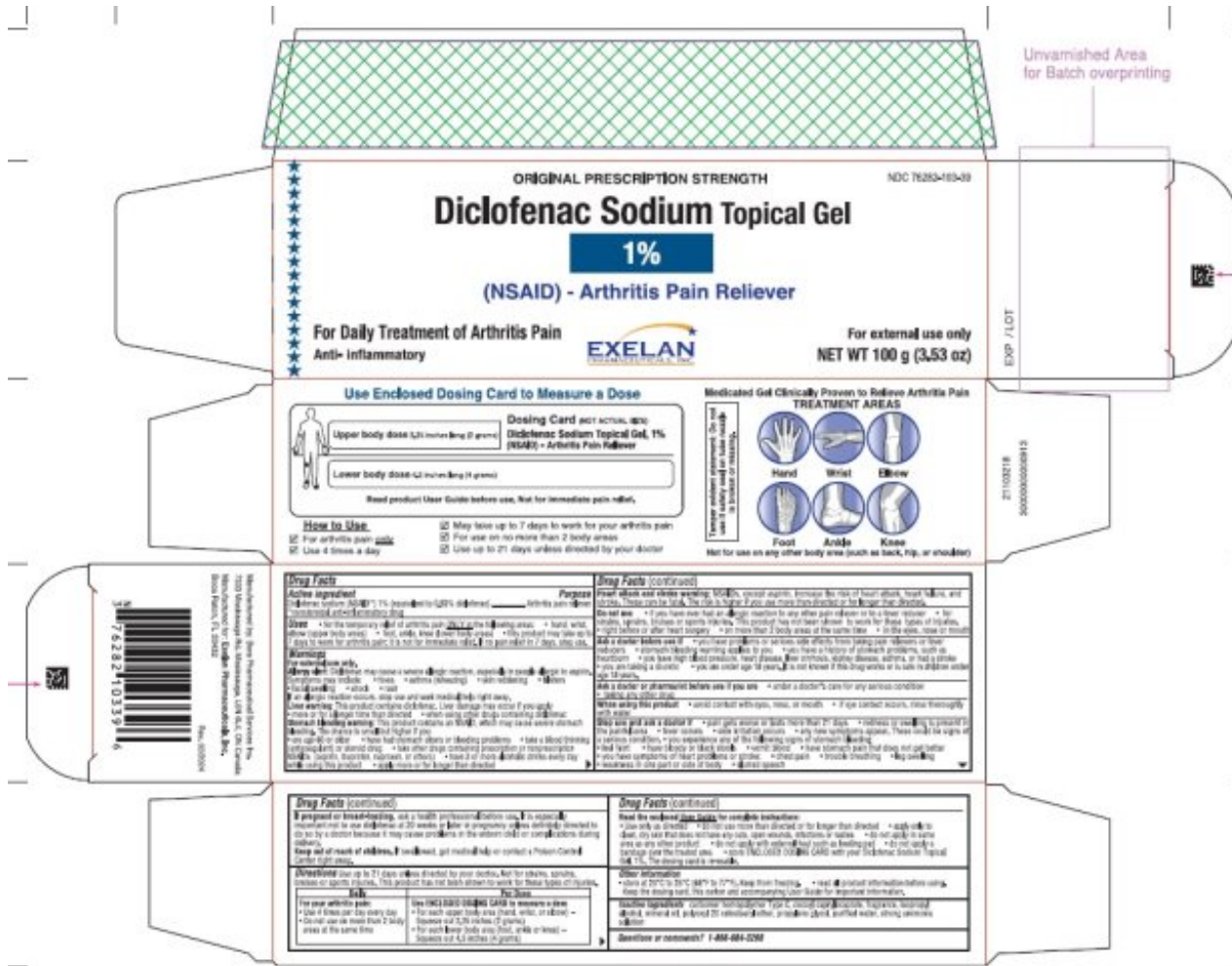
For Daily Treatment of Arthritis Pain

For external use only

Anti-inflammatory

NET WT 100 g (3.53 oz)

Unvarnished Area for Batch overprinting



# DICLOFENAC SODIUM

diclofenac sodium gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76282-103
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	10 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76282-103-39	1 in 1 CARTON	07/30/2024	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209903	07/30/2024	

**Labeler** - EXELAN PHARMACEUTICALS INC. (967795266)

**Registrant** - Cipla Limited (650138746)

### Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	manufacture(76282-103) , analysis(76282-103)

### Establishment

Name	Address	ID/FEI	Business Operations
Bora Pharmaceutical Services Inc		205556368	analysis(76282-103) , manufacture(76282-103)

Revised: 8/2024

EXELAN PHARMACEUTICALS INC.