

# **DICLOFENAC SODIUM- diclofenac sodium gel**

## **Sportpharm LLC**

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### **Diclofenac Sodium gel**

#### **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 the age of 18 years. It is not known if this drug works or is safe in children under the age of 18 years.

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

- 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 of side of body
  - slurred speech

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important to not 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**

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) 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.

Daily	Per Dose
<b>For your arthritis pain:</b> <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>	<b>Use ENCLOSED DOSING CARD to measure a dose</b> <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 Guidefor 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 areas as any other product
- do not apply with external heat such as a 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.

**Other information**

- store at 20° to 25°C (68° 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?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

**Medguide**

Use enclosed dosing card to measure a dose

**Diclofenac Sodium Topical Gel, 1%****(NSAID) - arthritis pain reliever**

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

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

**Dosing Card (NOT ACTUAL SIZE)**

**Read product User Guide before use**

**Not for immediate pain relief**

**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 a doctor

**Package Label**

Relabeled For:

**SPORTPHARM**

Diclofenac Sodium Topical Gel, 1% (NSAID)

NDC: 85766-136-01

Qty: 100

Distributed By: RUGBY LABORATORIES

Source NDC: 0536-1294-97

Description: 100 g gel in 1 tube

Lot #: XXXXXXXX

Exp:

Batch #: XXXXXXXX

Drug Status: OTC

Packaged By: Enovachem Pharmaceuticals Torrance, CA 90501

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0385766 13601 0

(17)

(10) XXXXXXXX

(21)

Diclofenac Sodium Topical Gel, 1% (NSAID)

NDC: 85766-136-01

S/N:

Qty: 100

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NDC: 85766-136-01

S/N:

Qty: 100

## DICLOFENAC SODIUM

diclofenac sodium gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85766-136(NDC:0536-1294)
Route of Administration	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 (UNII: 4Q93RCW27E)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
AMMONIA (UNII: 5138Q19F1X)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

Marketing Start      Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85766-136-01	1 in 1 CARTON	01/14/2026	
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	ANDA208077	09/14/2020	

**Labeler -** Sportpharm LLC (125298538)