

# DICLOFENAC SODIUM- diclofenac sodium gel

## CVS Pharmacy

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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 not to use this product during the last 3 months of 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
<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 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

### **Med Guide**

Use enclosed dosing card to measure a dose

Diclofenac Sodium Topical Gel, 1% (NSAID) - arthritis pain reliever  
Dosing Card (NOT ACTUAL SIZE) 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 a doctor

#### TREATMENT AREAS

- Hand
- Wrist
- Elbow
- Foot
- Ankle
- Knee

Not for use on any other body area (such as back, hip, or shoulder)

### **Principal display panel**

COMPARE TO the active ingredient in Voltaren® Arthritis Pain Topical Gell

ORIGINAL PRESCRIPTION STRENGTH

Diclofenac Sodium Topical Gel, 1% (NSAID)

ARTHRITIS PAIN RELIEVER

- Medicated gel clinically proven to relieve arthritis pain
- For daily treatment of arthritis pain
- Anti-inflammatory

**For External Use only**

NET WT OZ (g)

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Voltaren® Arthritis Pain Topical Gel.

**TAMPER EVIDENT STATEMENT: DO NOT USE IF FOIL SEAL ON TUBE OPENING IS BROKEN OR MISSING.**

**Distributed by: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

**Package Label**



Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C</b> (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)	

### Product Characteristics

<b>Color</b>	white (white to off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-974-17	1 in 1 CARTON	05/03/2021	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69842-974-35	1 in 1 CARTON	05/03/2021	
2		100 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69842-974-53	1 in 1 CARTON	05/03/2021	
3		150 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:69842-974-06	2 in 1 CARTON	05/03/2021	
4		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	05/03/2021	

**Labeler** - CVS Pharmacy (062312574)