

**ARTHRITIS PAIN- diclofenac sodium topical gel, 1% gel**  
**Strategic Sourcing Services, LLC**

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

**Active ingredient**

Diclofenac sodium (NSAID\*) 1%  
\*nonsteroidal anti-inflammatory drug

**Inactive ingredients**

Inactive ingredients:

Carbomer Homopolymer Type C, Coco-Caprylate/caprate, Isopropyl Alcohol, Mineral Oil, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Purified Water, Strong Ammonia Solution

**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 non-prescription 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 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 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% Arthritis Pain. The dosing card is re-usable.

### **Other information**

- Store at 20-25°C (68°F - 77°F). Keep from freezing.
- read all product information before using. Keep the dosing card, the carton and accompanying User guide for important information.

### **Inactive ingredients**

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

### **Question and comments 1-833-285-4151**

## **PRINCIPAL DISPLAY PANEL**

Arthritis Pain

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For external use only

For daily Treatment of Arthritis Pain Anti-Inflammatory

Net Wt 3.53 oz (100g)

# ARTHRITIS PAIN

diclofenac sodium topical gel, 1% gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-0143
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DICLOFENAC SODIUM</b> (UNII: QTG126297Q) (DICLOFENAC - UNII:14408QL0L1)	DICLOFENAC SODIUM	10 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M41630Z)	
<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
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**Drug Facts (continued)**

**Directions:** For external use only. For Daily Treatment of Arthritis Pain. **ANTI-INFLAMMATORY**

**Warnings:** Do not use if you are allergic to any of the ingredients listed on the label. Do not use if you are pregnant, breastfeeding, or planning to become pregnant. Do not use if you are taking other NSAIDs. Do not use if you are taking other pain relievers. Do not use if you are taking other blood thinners. Do not use if you are taking other drugs that may interact with this product. Do not use if you are taking other drugs that may increase the risk of heart attack, stroke, or other serious cardiovascular events. Do not use if you are taking other drugs that may increase the risk of kidney problems. Do not use if you are taking other drugs that may increase the risk of liver problems. Do not use if you are taking other drugs that may increase the risk of stomach ulcers. Do not use if you are taking other drugs that may increase the risk of bleeding. Do not use if you are taking other drugs that may increase the risk of dizziness. Do not use if you are taking other drugs that may increase the risk of drowsiness. Do not use if you are taking other drugs that may increase the risk of constipation. Do not use if you are taking other drugs that may increase the risk of diarrhea. Do not use if you are taking other drugs that may increase the risk of nausea. Do not use if you are taking other drugs that may increase the risk of vomiting. Do not use if you are taking other drugs that may increase the risk of indigestion. Do not use if you are taking other drugs that may increase the risk of heartburn. Do not use if you are taking other drugs that may increase the risk of acid reflux. Do not use if you are taking other drugs that may increase the risk of gas. Do not use if you are taking other drugs that may increase the risk of bloating. Do not use if you are taking other drugs that may increase the risk of constipation. Do not use if you are taking other drugs that may increase the risk of diarrhea. Do not use if you are taking other drugs that may increase the risk of nausea. Do not use if you are taking other drugs that may increase the risk of vomiting. Do not use if you are taking other drugs that may increase the risk of indigestion. Do not use if you are taking other drugs that may increase the risk of heartburn. Do not use if you are taking other drugs that may increase the risk of acid reflux. Do not use if you are taking other drugs that may increase the risk of gas. Do not use if you are taking other drugs that may increase the risk of bloating.

**How to Use:** For external use only. For Daily Treatment of Arthritis Pain. **ANTI-INFLAMMATORY**

**Use Enclosed Dosing Card to Measure a Dose:** Dosing Card NOT ACTUAL SIZE. Read enclosed 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)

**Warnings:** Do not use if you are allergic to any of the ingredients listed on the label. Do not use if you are pregnant, breastfeeding, or planning to become pregnant. Do not use if you are taking other NSAIDs. Do not use if you are taking other pain relievers. Do not use if you are taking other blood thinners. Do not use if you are taking other drugs that may interact with this product. Do not use if you are taking other drugs that may increase the risk of heart attack, stroke, or other serious cardiovascular events. Do not use if you are taking other drugs that may increase the risk of kidney problems. Do not use if you are taking other drugs that may increase the risk of liver problems. Do not use if you are taking other drugs that may increase the risk of stomach ulcers. Do not use if you are taking other drugs that may increase the risk of bleeding. Do not use if you are taking other drugs that may increase the risk of dizziness. Do not use if you are taking other drugs that may increase the risk of drowsiness. Do not use if you are taking other drugs that may increase the risk of constipation. Do not use if you are taking other drugs that may increase the risk of diarrhea. Do not use if you are taking other drugs that may increase the risk of nausea. Do not use if you are taking other drugs that may increase the risk of vomiting. Do not use if you are taking other drugs that may increase the risk of indigestion. Do not use if you are taking other drugs that may increase the risk of heartburn. Do not use if you are taking other drugs that may increase the risk of acid reflux. Do not use if you are taking other drugs that may increase the risk of gas. Do not use if you are taking other drugs that may increase the risk of bloating.

**Drug Facts (continued)**







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

NET WT 3.53 oz (100 g)

 Hand  
 Wrist  
 Elbow  
 Foot  
 Ankle  
 Knee

**TREATMENT AREAS**

Medicated Gel  
Clinically Proven  
to Relieve  
Arthritis Pain

For external use only

<b>1</b>	NDC:70677-0143-1	1 in 1 CARTON	07/06/2022	03/31/2025
<b>1</b>		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	ANDA210986	07/06/2022	

**Labeler** - Strategic Sourcing Services, LLC (116956644)

Revised: 11/2024

Strategic Sourcing Services, LLC