

**ARTHRITIS PAIN RELIEVER- diclofenac sodium gel**  
**Harris Teeter, LLC**

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**Diclofenac Sodium 1 percent Gel AML**

**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 diclofenac at 20 weeks 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 9 AM- 5 PM EST

### **Med Guide**

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)] Dosing Card (NOT ACTUAL SIZE)  
[Lower body dose 4.5 inches long (4 grams) 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

### **Principal display panel**

†Compare to the active ingredient in Voltaren® Arthritis Pain Topical Gel

Diclofenac Sodium

Topical Gel, 1%

Arthritis Pain Reliever (NSAID)

Original Prescription Strength

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 GlaxoSmithKline Consumer

Healthcare Holdings (US) LLC, 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:**

**HARRIS TEETER, LLC**

**MATTHEWS, NC 28105**

**Package Label**

**Drug Facts** (continued)

**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 (OAT) in the following areas: hand, wrist, elbow (upper body areas), neck, 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. **Alergy alert:** Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include hives (swelling), skin redness, blisters, and facial swelling. Other drugs containing diclofenac, 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 other drugs containing diclofenac; take a blood thinning (anticoagulant) or steroid drug; take other drugs containing prescription NSAIDs (aspirin, ibuprofen, naproxen, or others); have a or more alcoholic drinks every day while using the 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. This product has not been shown to work for these types of injuries. This product has not been shown to work for these types of injuries. This product has not been shown to work for these types of injuries.

**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. This product has not been shown to work for these types of injuries. This product has not been shown to work for these types of injuries.

**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; you have a history of stomach problems, such as heartburn; you have high blood pressure, heart disease, 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.

**When using this product:** avoid contact with eyes, nose, or mouth; if eye contact occurs, rinse thoroughly with water.

**Ask a doctor or pharmacist before use if you are:** taking any other drug; under a doctor's care for any serious condition; taking any other drug.

**Keep this and all other medicines out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**20 weeks or later in pregnancy unless directed by your doctor.** 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.

**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 your doctor

**Compare to the active ingredient in Voltaren® Arthritis Pain Topical Gel**

**Diclofenac Sodium Topical Gel, 1%**

**Arthritis Pain Reliever (NSAID)**

Original Prescription Strength  
Medicated Gel Clinically Proven to Relieve Arthritis Pain  
For Daily Treatment of Arthritis Pain  
Anti-inflammatory  
For External Use Only

**Net wt. 1.76 oz (50 g)**

**Drug Facts** (continued)

**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.

**Read the enclosed User Guide for complete instructions:** use only as directed; do not use more than directed; do not apply 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.

**Use ENCLOSED DOSING CARD to measure a dose**

Per Dose	For your arthritis pain:
Use ENCLOSED DOSING CARD to measure a dose	Use 4 times per day every day
For each upper body area (hand, wrist, or elbow) - Squeeze out 2.25 inches (2 grams)	Do not use on more than 2 body areas at the same time
For each lower body area (foot, ankle, or knee) - Squeeze out 4.5 inches (4 grams)	

**Questions or comments?** Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Inactive ingredients:** carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxy 20 ceteostearyl ether, propylene glycol, purified water, strong ammonia solution

**Treatment areas:** Hand, Wrist, Elbow, Foot, Ankle, Knee

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

**PROUDLY DISTRIBUTED BY:** HARRIS TEETER, LLC  
MATTWEWS, NC 28105  
1-800-422-6111 or hteeter.com

**yourPharmacist.**

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

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Lot No.:  
Exp. Date:

**HARRIS TEETER Arthritis Pain Reliever**

ARTHROSIS PAIN RELIEVER			
diclofenac sodium gel			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69256-012
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:14408QL0L1)	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: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
AMMONIA (UNII: 5138Q19F1X)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-012-17	1 in 1 CARTON	01/29/2021	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69256-012-35	1 in 1 CARTON	01/29/2021	
2		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	01/29/2021	

**Labeler** - Harris Teeter, LLC (048463103)