

ARTHRITIS PAIN RELIEVER- diclofenac sodium gel
Chain Drug Consortium, LLC

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

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
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

Principal display panel

†COMPARE TO THE ACTIVE INGREDIENT IN VOLTAREN® ARTHRITIS PAIN TOPICAL GEL ORIGINAL PRESCRIPTION STRENGTH

Arthritis Pain Relieving Gel

DICLOFENAC SODIUM TOPICAL GEL, 1% (**NSAID**)

- 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.

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

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

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

Distributed by: Pharmacy Value Alliance, LLC

407 East Lancaster Avenue

Wayne, PA 19087

Package Label

Drug Facts

Active ingredient Diclofenac sodium (NSAID) 1% (equivalent to 0.97% diclofenac).

Purpose Arthritis pain reliever.

Uses For the temporary relief of arthritis pain (OA, RA) in the following areas: Hand, wrist, elbow, foot, ankle, or knee.

Warnings Do not use if you have had a recent heart attack. Do not use if you have had a recent stroke. Do not use if you have had a recent heart failure. Do not use if you have had a recent heart attack, heart failure, or stroke. Do not use if you are pregnant or breastfeeding. Do not use if you have had a recent heart attack, heart failure, or stroke. Do not use if you are pregnant or breastfeeding.

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.

Other facts This product is not for use on any other body area such as back, hip, or shoulder.

Read the enclosed dosing card before use. Keep the dosing card, this carton and accompanying User Guide for important information.

Read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.

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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



Premier Value Arthritis Pain Relieving Gel Diclofenac Sodium Topical Gel, 1% (NSAID)

ARTHRITIS PAIN RELIEVER diclofenac sodium gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-171
Route of Administration	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:68016-171-50	1 in 1 CARTON	12/31/2022	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68016-171-00	1 in 1 CARTON	12/31/2022	
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	12/31/2022	

Labeler - Chain Drug Consortium, LLC (101668460)

