

DICLOFENAC SODIUM- diclofenac sodium gel

Rugby Laboratories, Inc.

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
For your arthritis pain: <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 	Use ENCLOSED DOSING CARD to measure a dose <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 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

Principal Display Panel

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

Original prescription strength

Diclofenac Sodium Topical Gel, 1% (NSAID) - Arthritis Pain Reliever

For daily treatment of arthritis pain / Anti-inflammatory

Medicated gel clinically proven to relieve arthritis pain

For external use only

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Voltaren® Arthritis Pain Topical Gel.

Distributed by: RUGBY LABORATORIES

Indianapolis, IN 46268

(800) 616-2471

www.majorpharmaceuticals.com

Package Label

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)

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

For daily treatment of arthritis pain/Anti-inflammatory

Medicated gel clinically proven to relieve arthritis pain
For external use only

NET WT 1.76 OZ (50 g)

NDC 0536-1294-34
Compare to the active ingredient in
Voltaren® Arthritis Pain Topical Gel†

Drug Facts (continued)

Active ingredients: carbomer homopolymer Type C, cocoyl caprylocaprate, fragrance, isopropyl alcohol, mineral oil, polyoxy 20 castorbean glycol, propylene glycol, purified water, strong ammonia solution

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

Drug Facts (continued)

For your arthritis pain:


Daily ■ Use 4 times per day every day

Use ENCLOSED DOSING CARD to measure a dose

Per Dose ■ For each upper body area (hand, wrist, or elbow) ■ 2.5 inches (2 grams)
■ For each lower body area (foot, ankle, or knee) ■ 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 ■ do not apply with external heat such as a heating pad, or for areas that do not have any cuts, open wounds, infections, or rashes ■ do not apply to same areas as any of your other product ■ do not apply to 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.

Hand  **Elbow**  **Foot**  **Ankle**  **Knee** 


Treatment areas

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

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Product Type	HUMAN OTC DRUG	Item Code (Source)	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				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1294-97	1 in 1 CARTON	09/14/2020	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0536-1294-34	1 in 1 CARTON	09/14/2020	
2		50 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0536-1294-31	1 in 1 CARTON	09/14/2020	
3		150 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 - Rugby Laboratories, Inc. (079246066)

