

ARTHRITIS PAIN RELIEVER- diclofenac sodium gel
P & L Development, 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 not to 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 caprylocaprata, 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®

pain relief gel 1%

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:

PL Developments

200 Hicks Street

Westbury, NY 11590

Package Label

<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are: ■ under a doctor's care for any serious condition ■ taking any other drug ■ 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. ■ you are taking a diuretic ■ you have high blood pressure, heart disease, liver disease, kidney disease, asthma, or had a stroke ■ you have a history of stomach problems, such as heartburn ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers</p> <p>Stop use and ask a doctor if: ■ pain gets worse or lasts more than 7 days ■ redness or swelling is present in the painful area ■ fever occurs ■ skin irritation occurs ■ any new symptoms appear ■ you have symptoms of heart problems or stroke: ■ chest pain ■ trouble breathing ■ leg swelling ■ you have bloody or black stools ■ vomit blood ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ dizziness ■ weakness in one part or side of body ■ slurred speech</p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use diclofenac at 20 weeks or later in pregnancy unless specifically 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.</p> <p>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.</p>	<p>Drug Facts</p> <p>Active ingredient Diclofenac sodium (NSAID), 1% (equivalent to 0.93% diclofenac).....Arthritis pain reliever, nonsteroidal anti-inflammatory drug</p> <p>Purpose Arthritis pain reliever</p> <p>Warnings</p> <p>■ For external use only. Allergic alert: Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. 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 longer than directed ■ when using other drugs containing diclofenac</p> <p>■ 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 other drugs containing aspirin or steroid drug ■ have a blood thinning (anticoagulant) or steroid drug</p> <p>■ 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.</p> <p>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.</p> <p>■ 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.</p>
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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

Let No.:
Exp. Date:

PLD 98929 F009455

3 59726 101235 5

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

Compare to the active ingredient in Voltaren® Arthritis Pain Topical Gel†
NDC 59726-012-53

pain relief gel 1%

diclofenac sodium topical gel, 1%
arthritis pain reliever (NSAID)

ready incase

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 3.53 oz (100 g)

<p>Drug Facts (continued)</p> <p>■ read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.</p> <p>Inactive ingredients carbomer homopolymer type C, cocoyl caprylate, fragrance, triacetin, isopropyl alcohol, mineral oil, polyoxy 20 castorbean ether, propylene glycol, purified water, strong ammonia solution</p> <p>Questions or comments? Call 1-877-753-3955 Monday-Friday 9AM-5PM EST</p> <p>This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Voltaren® Arthritis Pain Topical Gel.</p> <p>Distributed by: PL Developments 200 Hicks Street Westbury, NY 11590</p> <p>Treatment areas: </p> <p>Not for use on any other body areas (such as back, hip, or shoulder)</p>	<p>Drug Facts (continued)</p> <p>For your arthritis pain:</p> <table border="1"> <tr> <th>Per Dose</th> <th>Daily</th> </tr> <tr> <td>Use ENCLOSED DOSING CARD to measure a dose</td> <td>Use 4 times per day every day</td> </tr> <tr> <td>■ For each upper body area (hand, wrist, or elbow) – squeeze out 2.25 inches (2 grams)</td> <td>■ Do not use on more than 2 body areas at the same time</td> </tr> <tr> <td>■ For each lower body area (foot, ankle, or knee) – squeeze out 4.5 inches (4 grams)</td> <td></td> </tr> </table> <p>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 other products ■ do not apply with external heat such as a heating pad ■ do not apply a bandage over the treated area</p> <p>■ Store ■ store at 25°C (68° to 77°F). Keep from freezing.</p> <p>■ Other information ■ store at 25°C (68° to 77°F). Keep from freezing.</p> <p>■ Store ■ store at 25°C (68° to 77°F). Keep from freezing.</p>	Per Dose	Daily	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)	
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READYinCASE Arthritis Pain Reliever

ARTHRITIS PAIN RELIEVER

diclofenac sodium gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-012
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: 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:59726-012-53	1 in 1 CARTON	06/25/2021	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59726-012-50	1 in 1 CARTON	06/25/2021	
2		50 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	06/25/2021	

Labeler - P & L Development, LLC (800014821)

Revised: 12/2022

P & L Development, LLC