

# DICLOFENAC SODIUM- diclofenac sodium gel

## Walgreens

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### Diclofenac Sodium gel DELISTED

#### 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:
  - head, 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><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 caprylocaprato, 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

**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 (2grams)

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

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

**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% (NSAD) / ARTHRITIS RELIEVER

Anti-inflammatory

- For daily treatment of arthritis pain

FOR EXTERNAL USE ONLY

NET WT OZ (g)

††This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holding (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: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

Package label

**Drug Facts (continued)**

**Active ingredient** Diclofenac sodium (NSAID) 1% (equivalent to 0.9% diclofenac)

**Purpose** Arthritis pain reliever

**Uses** For the temporary relief of arthritis pain (DNL) 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 ■ skin redness ■ blisters ■ facial swelling ■ rash. If an allergic reaction may occur if you apply; stop use and seek medical help right away. **Liver warning:** This product contains diclofenac. Liver damage may occur if you use for a longer time than directed. **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. **Stomach bleeding warning:** This product contains an NSAID, which may cause bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription aspirin, naproxen, ibuprofen, rofecoxib, or others ■ have 5 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** ■ 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. ■ for the eyes, nose, or mouth ■ after heart surgery ■ on more than 2 body areas at the same time

**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, the carton and accompanying User Guide for important information.

■ do not apply ointment over the treated area ■ do not apply ointment in same areas as any other product ■ do not apply with external heat such as a heating pad ■ for longer than directed ■ apply to clean, dry skin that does not have any cuts, open wounds, infections or rashes ■ use only as directed ■ do not use more than directed

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

■ do not apply ointment over the treated area ■ do not apply ointment in same areas as any other product ■ do not apply with external heat such as a heating pad ■ for longer than directed ■ apply to clean, dry skin that does not have any cuts, open wounds, infections or rashes ■ use only as directed ■ do not use more than directed

■ do not use on more than 2 body areas at the same time ■ use 4 times per day every day ■ use 4 times per day every day

For your arthritis pain:

Use ENCLOSED DOSING CARD to measure a dose

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)

Per Dose

**Drug Facts (continued)**

**Questions or comments?** Call 1-877-873-3908 Monday-Friday 9AM-5PM EST

Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. ■ This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Voltaren® Arthritis Pain Topical Gel.

Product of India

Treatment Areas

Hand Wrist Elbow Foot Ankle Knee

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

200 WILMOT RD., DEERFIELD, IL 60015  
DISTRIBUTED BY: WALGREEN CO.  
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**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

**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

**Drug Facts (continued)**

**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. ■ 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 blood or black stools ■ chest pain ■ trouble breathing ■ fog swelling ■ weakness in one part or side of body ■ slurred speech ■ vomit blood ■ have stomach pain that does not get better

**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.

**Drug Facts (continued)**

**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 blood or black stools ■ chest pain ■ trouble breathing ■ fog swelling ■ weakness in one part or side of body ■ slurred speech ■ vomit blood ■ have stomach pain that does not get better

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Lot No.:  
Exp. Date:

ITEM 842846 WH1042-0293-L

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

3 119177 21590 7

PLD-0262B FC008459

ORIGINAL PRESCRIPTION STRENGTH NDC 0383-1210-17

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

# Arthritis Pain Relieving Gel

DICLOFENAC SODIUM TOPICAL GEL, 1% (NSAID) / ARTHRITIS PAIN RELIEVER

Anti-inflammatory • For daily treatment of arthritis pain

NET WT 1.76 OZ (50 g) FOR EXTERNAL USE ONLY

**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, the carton and accompanying User Guide for important information.

■ do not apply ointment over the treated area ■ do not apply ointment in same areas as any other product ■ do not apply with external heat such as a heating pad ■ for longer than directed ■ apply to clean, dry skin that does not have any cuts, open wounds, infections or rashes ■ use only as directed ■ do not use more than directed

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

■ do not apply ointment over the treated area ■ do not apply ointment in same areas as any other product ■ do not apply with external heat such as a heating pad ■ for longer than directed ■ apply to clean, dry skin that does not have any cuts, open wounds, infections or rashes ■ use only as directed ■ do not use more than directed

■ do not use on more than 2 body areas at the same time ■ use 4 times per day every day ■ use 4 times per day every day

For your arthritis pain:

Use ENCLOSED DOSING CARD to measure a dose

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)

Per Dose

**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

**Drug Facts (continued)**

**Questions or comments?** Call 1-877-873-3908 Monday-Friday 9AM-5PM EST

Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. ■ This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Voltaren® Arthritis Pain Topical Gel.

Product of India

Treatment Areas

Hand Wrist Elbow Foot Ankle Knee

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

200 WILMOT RD., DEERFIELD, IL 60015  
DISTRIBUTED BY: WALGREEN CO.  
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**How to use**

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- Use 4 times a day
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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

**WALGREENS Arthritis Pain Relieving Gel**

W30RG0122-F  
REV-0323

# DICLOFENAC SODIUM

diclofenac sodium gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-1210
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DICLOFENAC SODIUM</b> (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	10 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<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)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:0363-1210-53	1 in 1 CARTON	03/15/2021	12/15/2026
1		150 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0363-1210-35	1 in 1 CARTON	03/15/2021	12/15/2026
2		100 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0363-1210-17	1 in 1 CARTON	03/15/2021	12/15/2026
3		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	03/15/2021	12/15/2026

**Labeler** - Walgreens (008965063)

Revised: 4/2026

Walgreens