

DICLOFENAC SODIUM- diclofenac sodium topical gel, 1% gel
GERI-CARE PHARMACEUTICALS CORP

Diclofenac Sodium Topical Gel, 1%
(NSAID) - arthritis pain reliever

Active ingredient

Diclofenac sodium (NSAID*) 1%
*nonsteroidal anti-inflammatory drug

Inactive ingredients

Inactive ingredients:

Carbomer Homopolymer Type C, Coco-Caprylate/caprate, Isopropyl Alcohol, Mineral Oil, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Purified Water, Strong Ammonia Solution

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 non-prescription 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 age 18 years. It is not known if this drug works or is safe in children under age 18 years.

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 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 or side of body
- slurred speech

If pregnant or breast-feeding

ask a health professional before use. It is especially important not to use this product during the last 3 months 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 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 area as any other product
- do not apply with external heat such as heating pad
- do not apply a bandage over the treated area

store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel, 1% Arthritis Pain. The dosing card is re-usable.

Other information

- Store at 20-25°C (68°F - 77°F). Keep from freezing.
- read all product information before using. Keep the dosing card, the carton and accompanying User guide for important information.

Inactive ingredients

Carbomer homopolymer Type C, cocoyl caprylocaprates, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution.

Question and comments 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Carton Label - NDC 57896-140-01

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For external use only

For daily Treatment of Arthritis Pain Anti-Inflammatory

Net Wt 3.53 oz (100g)

<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> avoid contact with eyes, nose, or mouth if eye contact occurs, rinse thoroughly with water <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> pain gets worse or lasts more than 21 days redness or swelling is present in the painful area fever occurs any new symptoms appear. These could be signs of a serious condition. stomach bleeding or signs of stomach bleeding: you experience any of the following signs or black stools feel faint have bloody or black stools have stomach pain that does not get better vomit blood you have symptoms of heart problems or stroke: chest pain trouble breathing leg swelling weakness in one part or side of body slurred speech 	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever or 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 <p>ASK a doctor before use if</p> <ul style="list-style-type: none"> 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, heart disease, kidney disease, asthma, or had a stroke you are taking a diuretic you are under age 18 years. It is not known if this drug works or is safe in children <p>under age 18 years.</p>
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<p>Warnings</p> <p>For external use only</p> <p>Allergic Alert: Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives asthma (wheezing) skin reddening bleeds facial swelling shock rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>For the temporary relief of arthritis pain ONLY in the following areas:</p> <ul style="list-style-type: none"> hand, wrist, elbow (upper body areas) foot, ankle, knee (lower body areas) <p>If no pain relief in 7 days, stop use.</p> <p>This product may take up to 7 days to work for arthritis pain. It is not for immediate relief.</p> <p>Do not use if you are taking other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</p> <ul style="list-style-type: none"> 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. 	<p>LIFT HERE</p> <p>▲ LIFT FLAP FOR IMPORTANT DIRECTIONS & WARNINGS</p>
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Drug Facts Diclofenac sodium (NSAID) 1% Nonsteroidal anti-inflammatory drug	Uses Arthritis pain reliever
Drug Facts (continued) 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	

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)

Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.

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



NDC 57896-140-01

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

Diclofenac Sodium Topical Gel, 1%

(NSAID) - Arthritis Pain Reliever

NET WT 3.53 oz (100 g)

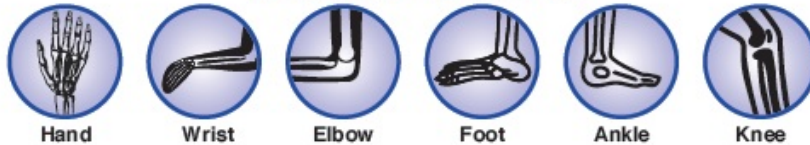
Original Prescription Strength

- For Daily Treatment of Arthritis Pain
- Anti-Inflammatory

For external use only

Medicated Gel Clinically Proven to Relieve Arthritis Pain

TREATMENT AREAS



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

Distributed by:
GERI-CARE PHARMACEUTICALS CORP.
1650 63rd Street
Brooklyn, NY 11204

Made in India Code : 60/DRUGS/3 61

**This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, PLC, distributor of Voltaren Arthritis Pain Gel.

REV: 10/20

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<p>Drug Facts (continued) 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 area as any other product do not apply with external heat such as heating pad do not apply a bandage over the treated area store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel. The dosing card is re-usable.</p> <p>Other Information Store at 20-25°C (68-77°F). Keep from freezing. 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 caprylocaprate, isopropyl alcohol, mineral oil, polyoxy 20 cetostearyl ether, propylene glycol, purified water, and strong ammonia solution.</p> <p>Questions or comments? 1-888-375-3784</p>	<p>Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use this product during the last 3 months 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 right away (1-800-222-1222). 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>Directions</p> <p>Daily For your arthritis pain: Use ENCLOSED DOSING CARD to measure a dose Use 4 times per day every day Do not use on more than 2 body areas at the same time</p> <p>Per 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)</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>Daily For your arthritis pain: Use ENCLOSED DOSING CARD to measure a dose Use 4 times per day every day Do not use on more than 2 body areas at the same time</p> <p>Per 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)</p>

diclofenac sodium topical gel, 1% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-140(NDC:43598-977)
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-140-01	1 in 1 CARTON	10/05/2021	
1		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	ANDA210986	10/05/2021	

Labeler - GERI-CARE PHARMACEUTICALS CORP (611196254)

Revised: 10/2021

GERI-CARE PHARMACEUTICALS CORP