

DICLOFENAC SODIUM- diclofenac sodium 1% gel
SOLA Pharmaceuticals

Diclofenac Sodium Gel 1%

(NSAID) - arthritis pain reliever

Active ingredient

Diclofenac sodium (NSAID*) 1%

*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 not 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 high 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 or 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 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 last 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 care 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 For arthritis pain:

Use 4 times per day every day

Do not use on more than 2 body areas at the same time

- **Per Dose (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)

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 the 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.

Questions and comments 1-866-747-7365

Principal Display Panel

Carton Label - 100g

NDC 70512-106-10

ORIGINAL PRESCRIPTION STRENGTH

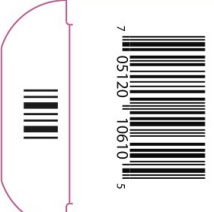
Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For daily Treatment of Arthritis Pain Anti-Inflammatory

For external use only

Net Wt. 3.53 oz (100 g)

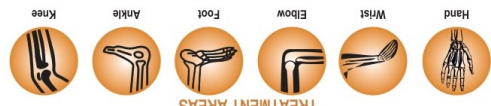


7 05120 10610 5

<p>Drug Facts (continued)</p> <p>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.</p> <p>Directions</p> <p>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> <table border="1" style="width: 100%;"><thead><tr><th>Daily</th><th>Per Dose</th></tr></thead><tbody><tr><td>For your arthritis pain: Use 4 times per day every day Do not use on more than 2 body areas at the same time</td><td>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)</td></tr></tbody></table>	Daily	Per Dose	For your arthritis pain: 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 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>Drug Facts (continued)</p> <p>Read the enclosed User Guide for complete instructions:</p> <ul style="list-style-type: none">use only as directeddo not use more than directed or for longer than directedapply only to clean, dry skin that does not have any cuts, open wounds, infections or rashesdo not apply in same area as any other productdo not apply with external heat such as heating paddo not apply a bandage over the treated areastore ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel. The dosing card is re-usable. <p>Other Information</p> <ul style="list-style-type: none">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>Inactive ingredients Carbomer homopolymer Type C, cetyl palmitate, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, and strong ammonia solution.</p> <p>Questions or comments? 1-866-747-7365</p>
Daily	Per Dose				
For your arthritis pain: 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 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)				

Unvarnished Area

Medicated Gel
Clinically Proven to
Relieve Arthritis
Pain



TREATMENT AREAS

Hand, Wrist, Elbow, Foot, Ankle, Knee

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

NET WT 3.53 oz (100 g)
(NSAID) - arthritis pain reliever
Diclofenac Sodium
Topical Gel, 1%
Original Prescription Strength
Anti-Inflammatory
For Daily Treatment of Arthritis Pain

SOLA PHARMACEUTICALS

Use Enclosed Dosing Card to Measure a Dose

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

Doing 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 more than 2 body areas

Use up to 21 days unless directed by your doctor

<p>Drug Facts</p> <p>Active ingredient Diclofenac sodium (NSAID) 1% nonsteroidal anti-inflammatory drug</p> <p>Purpose Arthritis pain reliever</p> <p>Uses</p> <ul style="list-style-type: none">for the temporary relief of arthritis pain ONLY in following areas:<ul style="list-style-type: none">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. <p>Warnings</p> <p>For external use only</p> <p>Allergy alert: Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none">hivesasthma (wheezing)skin reddeningblistersfacial swellingshockrash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p>	<p>Drug Facts (continued)</p> <p>Liver warning: This product contains diclofenac. Liver damage may occur if you apply more or for a longer time than directed</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is small but higher if you</p> <ul style="list-style-type: none">are age 65 or olderhave had stomach ulcers or bleeding problemstake a blood thinning (anticoagulant) or steroid drugtake other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)have 3 or more alcoholic drinks every day while using this productapply more or for longer than directed <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>
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Do not use

- if you have ever had an allergic reaction to any other pain reliever or to a fever reducer
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- 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.

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
- fever 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

Tube Label- 100g

NDC 70512-106-10

Diclofenac Sodium Topical Gel, 1%


(NSAID)- Arthritis pain reliever

For external use only

Net Wt 3.53 oz (100 g)

NDC 70512-0106-10

Diclofenac Sodium Topical Gel, 1%



(NSAID) - arthritis pain reliever

NET WT 3.53 oz (100 g)

To open tube: Unscrew cap and open the seal that covers the tube opening by using the spiked top of the cap. Firmly press the cap to remove the safety seal.

This tube does not contain full product information. Retain outer carton, dosing card and User Guide for full product uses, directions and warnings.

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


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
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■ 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
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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.
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.
Store at 20-25°C (68-77°F). Keep from freezing.

Made in India
Code : GO/DRUGS/361

Manufactured for:
SOLA PHARMACEUTICALS, LLC
Baton Rouge, LA 70810

For lot number and expiration date, see crimp of tube or carton. REV: 12/20 SDG1A/00



DICLOFENAC SODIUM

diclofenac sodium 1% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-106
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
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-106-10	1 in 1 CARTON	03/17/2021	
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	03/17/2021	

Labeler - SOLA Pharmaceuticals (080121345)

Revised: 3/2021

SOLA Pharmaceuticals