DICLOFENAC SODIUM- diclofenac sodium gel
Advanced Rx Pharmacy of Tennessee, LLC

Diclofenac Sodium 1% Gel

Active Ingredient

(NSAID) - arthritis pain reliever

Active ingredient

Diclofenac sodium (NSAID*) 1%

*nonsterodial anti-inflammatory drug

Purpose

Purpose

Arthritis pain reliever

Indications and Usage

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

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 contain 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 attach, heart failure, and stroke. These can be fatal. The rish is higher if you use more than directed or for longer than directed.

Do Not Use

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 Doctor

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 prohlems, 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 Doctor/Pharmacist

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

When using this product
- avoid contact with eyes, nose, or mouth
- if eye contact occurs, rinse thoroughly with water

Stop Use

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 heat problems or stroke
- chest pain
- trouble breathing
- leg swelling
- weakness in one part or side of body
- slurred speech

Pregnancy or Breast Feeding

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

Keep our of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Dosage & Administration

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 Safety Information

Other Information

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

Inactive Ingredients

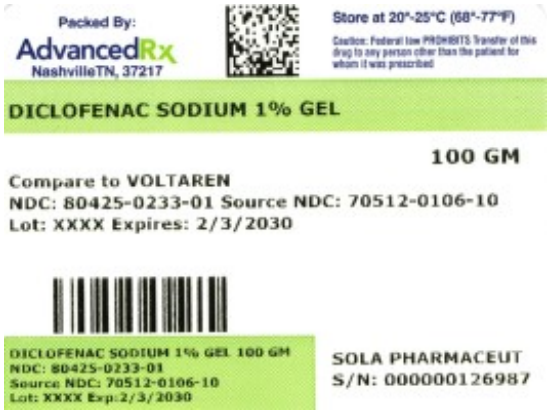
Inactive ingredients

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

Questions and Comments

Questions and comments 1-866-747-7365

Principal Display Panel



DICLOFENAC SODIUM

diclofenac sodium gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80425-0233(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
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
AMMONIA (UNII: 5138Q19F1X)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0233-1	1 in 1 CARTON	02/06/2023	
1		100 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA210986	02/06/2023	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0233)

Revised: 2/2023 Advanced Rx Pharmacy of Tennessee, LLC