DICLOFENAC SODIUM TOPICAL GEL 1%- diclofenac sodium topical gel, 1% gel
Kroger Company

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 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 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
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)

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

Inactive ingredients

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

Question and comments: 1-888-375-3784

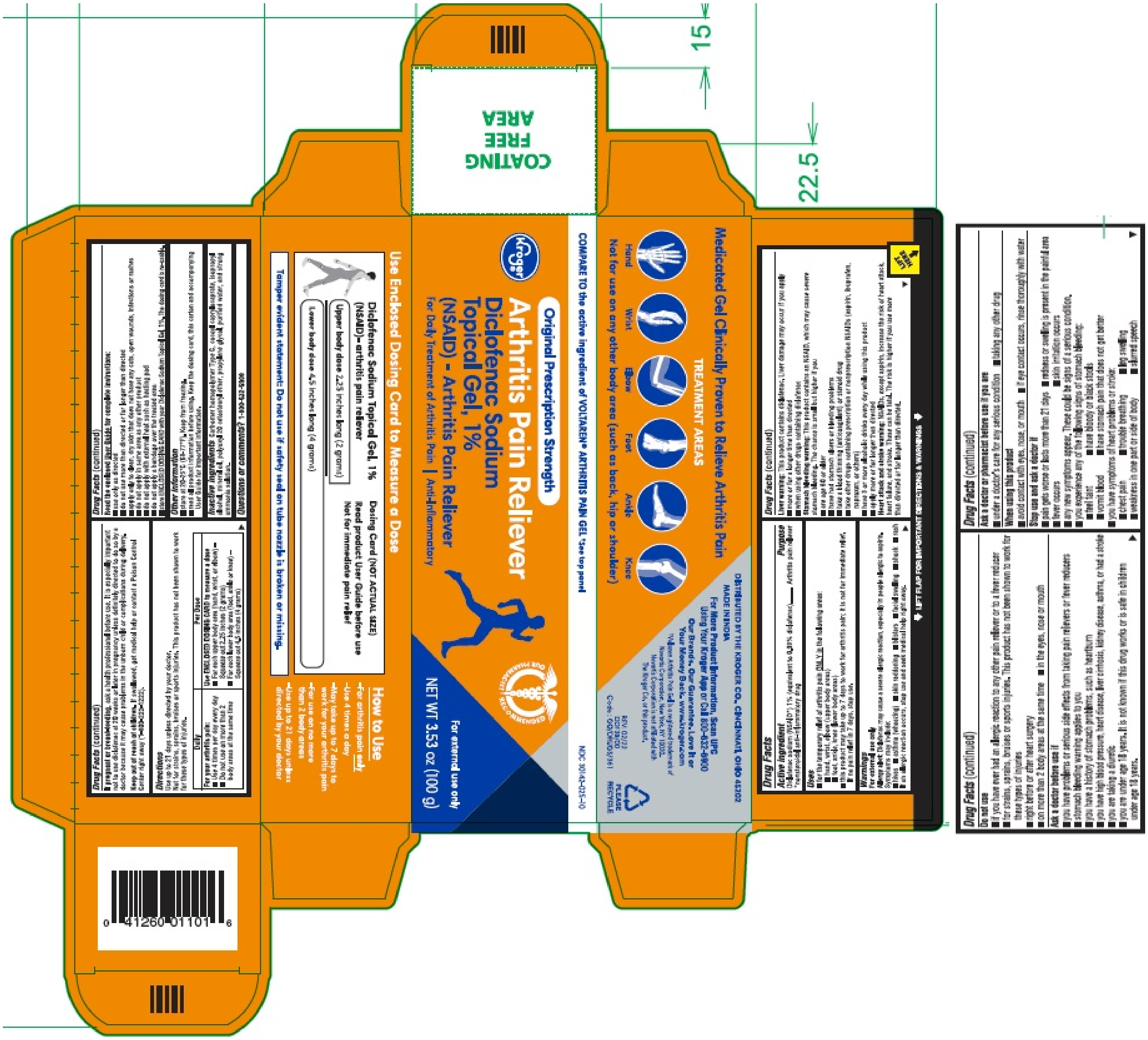
PRINCIPAL DISPLAY PANEL

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For external use only

For daily Treatment of Arthritis Pain Anti-Inflammatory



COATING FREE 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)
COMPARE TO the active ingredient of VOLTAREN® ARTHRITIS PAIN GEL *see top panel
Original Prescription Strength
Arthritis Pain Reliever
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)
Use Enclosed Dosing Card to Measure a Dose
Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.
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)
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
DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202
MADE IN INDIA
For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900
Our Brand. Our Guarantee. Love It or Your Money Back. www.kroger.com
PLEASE RECYCLE
Drug Facts
Drug Facts (continued)
LIFT FLAP FOR IMPORTANT DIRECTIONS & WARNINGS
0 41260 01101 6
15
22.5

Tube Label:

DICLOFENAC SODIUM TOPICAL GEL 1%

diclofenac sodium topical gel, 1% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-025
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: YRC528SWJY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
Ammonia (UNII: 5138Q19F1X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-025-50	1 in 1 CARTON	01/31/2021	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:30142-025-15	1 in 1 CARTON	01/31/2021	
2		150 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:30142-025-10	1 in 1 CARTON	06/13/2022	
3		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	01/31/2021	

Labeler - Kroger Company (006999528)

Revised: 12/2024 Kroger Company