DICLOFENAC SODIUM- diclofenac sodium gel
Akorn

Drug Facts

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:
  - 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 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 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 (1-800-222-1222).

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 areas (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% product. The dosing card is re-usable.

Other information

- store at 20 to 25ºC (68 to 77 ºF). 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 caprylocaprate, isopropyl alcohol, lavender herbal fragrance, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water and strong ammonia solution

Questions or comments?

Call **1-800-932-5676** weekdays (9:00 am to 5:00 pm) www.akorn.com

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Package/Label Principal Display Panel

AKORN

ORIGINAL PRESCRIPTION STRENGTH

NDC 50383-528-01

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

Diclofenac Sodium Topical Gel, 1% (NSAID)

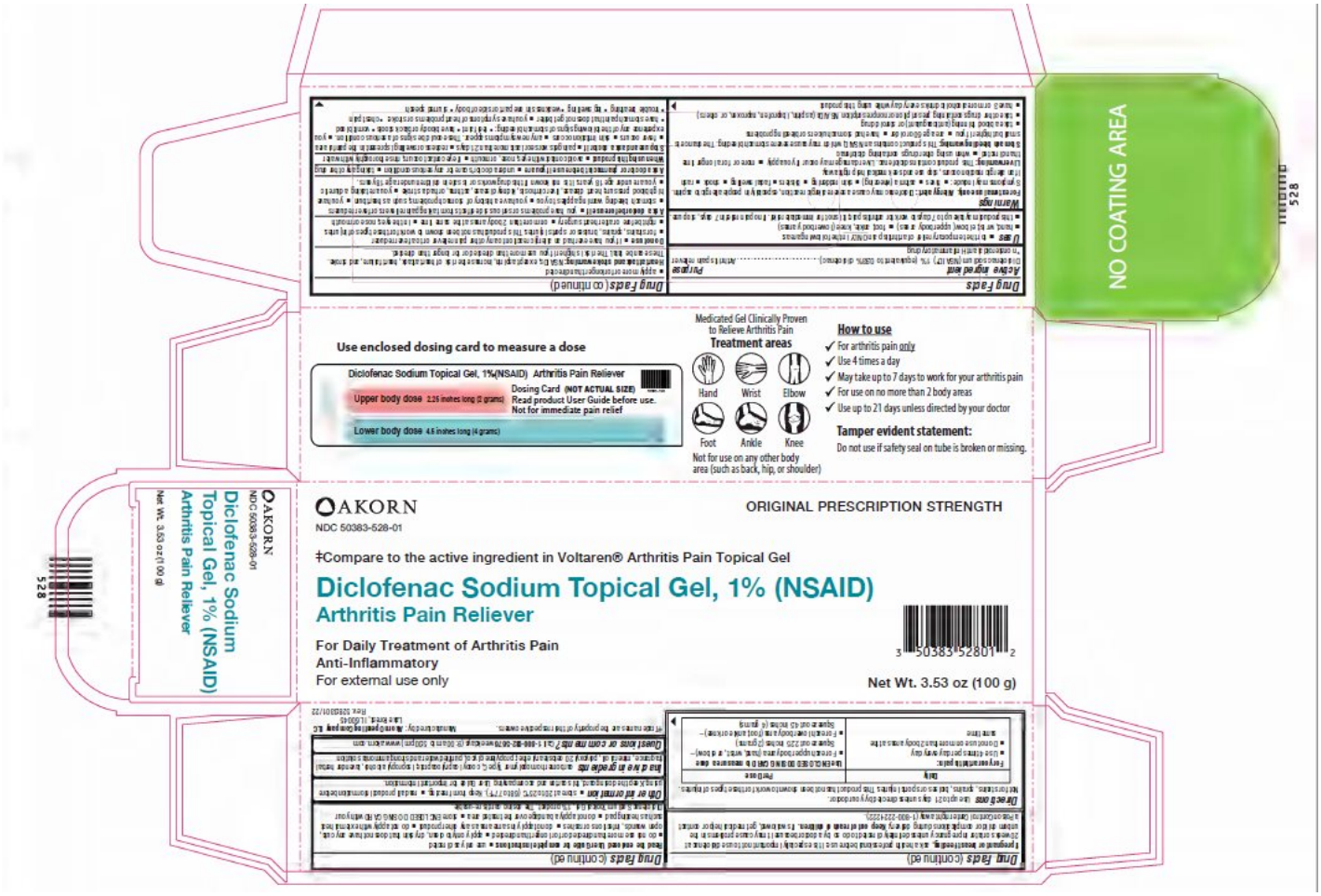
Arthritis Pain Reliever

For Daily Treatment of Arthritis Pain

Anti-inflammatory

For external use only

Net Wt. 3.53 oz (100 g)



DICLOFENAC SODIUM

diclofenac sodium gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50383-528
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**
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (Opaque)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50383-528-01	1 in 1 CARTON	12/31/2021	
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	ANDA209484	12/31/2021	

Labeler - Akorn (117696873)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn		117696873	MANUFACTURE(50383-528) , PACK(50383-528)

Revised: 4/2022 Akorn