DICLOFENAC SODIUM GEL- diclofenac sodium gel gel
Galloping LLC

Diclofenac sodium (NSAID*) 1% (equivalent to 0.93% diclofenac)

*nonsteroidal anti-inflammatory drug

Arthritis pain reliever

•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.

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.

•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

•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.

•under a doctor’s care for any serious condition
•taking any other drug

•avoid contact with eyes, nose, or mouth
•if eye contact occurs, rinse thoroughly with water

•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

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.

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.

Daily

For your 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

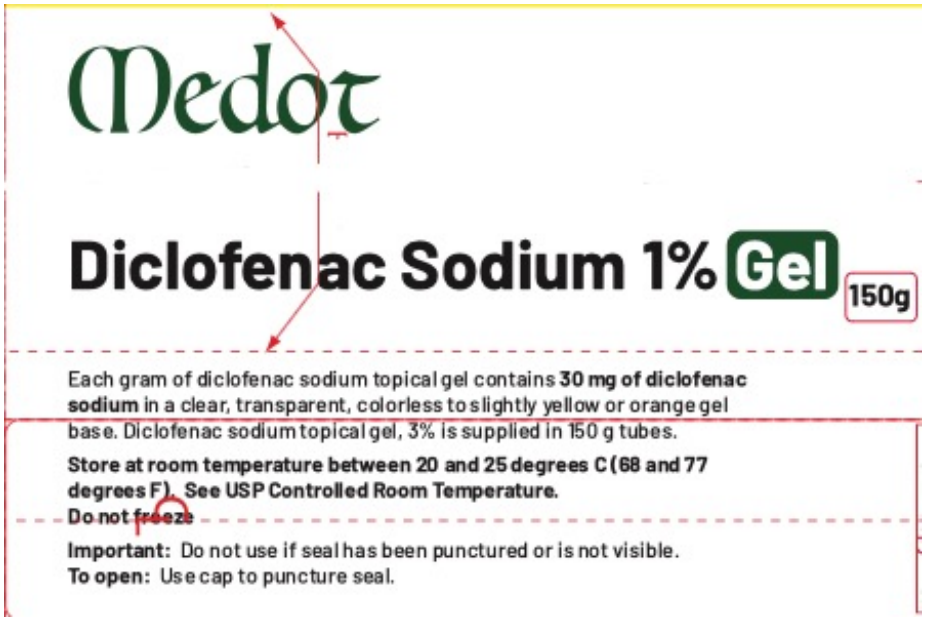
•For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)
•For each lower body area (foot, ankle or knee) –Squeeze out 4.5 inches (4 grams)

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 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.

•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.

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



DICLOFENAC SODIUM GEL

diclofenac sodium gel gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83136-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC (UNII: 144O8QL0L1) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83136-101-15	1 in 1 CARTON	05/28/2023	
1		150 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	ANDA211253	05/28/2023	

Labeler - Galloping LLC (118849262)

Establishment

Name	Address	ID/FEI	Business Operations
Gabar Health Sciences Corp.		118401847	manufacture(83136-101)

Revised: 5/2023 Galloping LLC