SYNAGEL- diclofinac sodium gel
Noor Brands Company, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Drug Facts

Active ingredient.

Diclofenac Sodium 1.0%

Purpose

Topical analgesic

Uses

- temporary relief from minor aches and pains associated with:
- simple backache
- arthritis
- strains
- bruises

Warnings

For external use only. Flammable. Keep away from fire or flame.

Do Not Use

- on wounds or damaged skin
- with a heating pad or external heat

When using this product

- use only as directed
- do not bandage tightly
- avoid contact with eyes, nose or mouth

Stop use and ask a doctor if

- skin redness or irritation occurs
- condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant of breastfeeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Adults and Children 12 years of age and older:

- Apply to affected area no more than 3 to 4 times daily
- Allow to dry without rubbing

Children 12 years or younger: ask a doctor

Inactive ingredients

alcohol, chitosan, glycerin, lactic acid, water

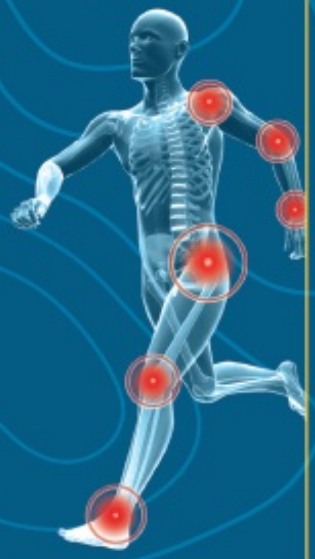
Product label

SYNAGEL™

PAIN RELIEF

Next-Generation Topical Gel

Fast-Acting Long-Lasting Relief



NO-TOUCH APPLICATOR

NET 0.5 FL OZ
(15mL)

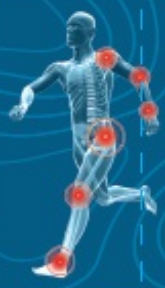
Non Printing Area

SYNAGEL™

PAIN RELIEF

Next-Generation Topical Gel

Fast-Acting Long-Lasting Relief



NO-TOUCH APPLICATOR

Distributed by:
Noor Brands Company, LLC
648 Southwest St.
High Point, NC 27260

Rev 0123

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NET 0.5 FL OZ
(15mL)

8 60006 23193 4

Non Printing Area

SYNAGEL™

PAIN RELIEF

NDC#

Next-Generation Topical Gel

Fast-Acting Long-Lasting Relief

NET 1.0 FL OZ
(30mL)

NO-TOUCH APPLICATOR

Distributed by:
Noor Brands Company, LLC
648 Southwest St.
High Point, NC 27260

Rev 0123

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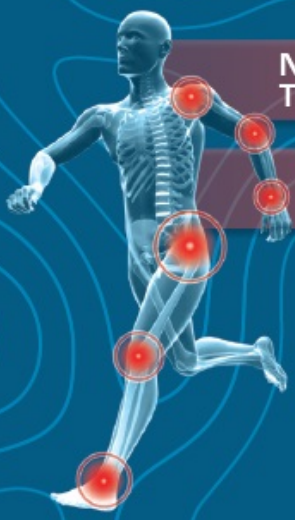
SYNAGEL™

PAIN RELIEF

NDC#



Next-Generation
Topical Gel

Fast-Acting
Long-Lasting Relief

Distributed by:
Noor Brands Company, LLC
648 Southwest St.
High Point, NC 27260

Rev 0123

NO-TOUCH APPLICATOR

8 60006 23194 1

NET 3.38 FL OZ
(100mL)

Drug Facts

Active ingredient — **Purpose**
Diclofenac Sodium 1.0% ..... Topical analgesic

Uses temporary relief from minor aches and pains associated with:
- simple backache
- arthritis
- strains
- bruises

Warnings

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Do Not Use
- on wounds or damaged skin
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When using this product
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- do not bandage tightly
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions **Adults and Children 12 years of age and older:**
- Apply to affected area no more than 3 to 4 times daily
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Children 12 years or younger: ask a doctor

Inactive Ingredients alcohol, chitosan, glycerin, lactic acid, water

SYNAGEL

diclofinac sodium gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82213-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLIGLUSAM (UNII: 82LKS4QV2Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82213-002-01	1 in 1 BLISTER PACK	11/02/2023	
1		14 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:82213-002-02	1 in 1 BOX	11/02/2023	
2		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
3	NDC:82213-002-03	1 in 1 BOX	11/02/2023	
3		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/02/2023	

Labeler - Noor Brands Company, LLC (118242423)

Establishment

Name	Address	ID/FEI	Business Operations
Noor Brands Company, LLC		118242423	manufacture(82213-002)

Revised: 11/2023 Noor Brands Company, LLC