

# **DICLOFENAC SODIUM- diclofenac sodium topical gel, 1% gel**

## **Simple Diagnostics**

-----

### **Diclofenac Sodium Topical Gel, 1%**

#### **(NSAID) - arthritis pain reliever**

#### **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 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.

<b>Daily</b>	<b>Per Dose</b>
<p><b>For your arthritis pain:</b></p> <ul style="list-style-type: none"> <li>• Use 4 times per day every day</li> <li>• Do not use on more than 2 body areas at the same time</li> </ul>	<p><b>Use ENCLOSED DOSING CARD to measure a dose</b></p> <ul style="list-style-type: none"> <li>• For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)</li> <li>• For each lower body area (foot, ankle or knee) –Squeeze out 4.5 inches (4 grams)</li> </ul>

**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 20-25 °C (68°F - 77°F). Keep from freezing.
- read all product information before using. Keep the dosing 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 1-833-285-4151**

**Tube Label- 100g**

**Tube Label - 100 g**

**NDC 62379-401-01**

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 (100g)**

<p><b>Drug Facts (continued)</b></p> <p>If pregnant or breast-feeding, 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.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Directions</b></p> <p>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.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Daily</th> <th style="width: 50%;">Per Dose</th> </tr> </thead> <tbody> <tr> <td> <p>For your arthritis pain:</p> <ul style="list-style-type: none"> <li>■ Use 4 times per day every day</li> <li>■ Do not use on more than 2 body areas at the same time</li> </ul> </td> <td> <p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> <li>■ For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)</li> <li>■ For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)</li> </ul> </td> </tr> </tbody> </table>	Daily	Per Dose	<p>For your arthritis pain:</p> <ul style="list-style-type: none"> <li>■ Use 4 times per day every day</li> <li>■ Do not use on more than 2 body areas at the same time</li> </ul>	<p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> <li>■ For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)</li> <li>■ For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p>Read the enclosed <b>User Guide</b> for complete instructions:</p> <ul style="list-style-type: none"> <li>■ Use only as directed</li> <li>■ Do not use more than directed or for longer than directed</li> <li>■ Apply only to clean, dry skin that does not have any cuts, open wounds, infections or rashes</li> <li>■ Do not apply in same area as any other product</li> <li>■ Do not apply with external heat such as heating pad</li> <li>■ Do not apply a bandage over the treated area</li> <li>■ Store ENCLOSED DOSING CARD with your Diclofenac Sodium Topical Gel. The dosing card is re-usable.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ Store at 20-25°C (68-77°F). Keep from freezing.</li> <li>■ Read all product information before using. Keep the dosing card, this carton and accompanying User Guide for important information.</li> </ul> <p><b>Inactive ingredients</b> Carbomer homopolymer Type C, cetyl palmitate, isopropyl alcohol, mineral oil, polyoxy (20 cetearyl) ether, propylene glycol, purified water, and strong ammonia solution.</p> <p><b>Questions or comments?</b> Contact customerservice@sampdiagnostics.com</p>
Daily	Per Dose				
<p>For your arthritis pain:</p> <ul style="list-style-type: none"> <li>■ Use 4 times per day every day</li> <li>■ Do not use on more than 2 body areas at the same time</li> </ul>	<p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> <li>■ For each upper body area (hand, wrist, or elbow) – Squeeze out 2.25 inches (2 grams)</li> <li>■ For each lower body area (foot, ankle or knee) – Squeeze out 4.5 inches (4 grams)</li> </ul>				

SDG3A00

REV: 12/20

Consumer Healthcare, LLC, a subsidiary of Volumental Arthritis Pain, Inc.  
 The product is manufactured or distributed by GalienMed/Inc.

**Medicated Gel**

**Clinically Proven to Relieve Arthritis Pain**

**TREATMENT AREAS**

Not for use on any other body area (such as back, hip, or shoulder)

NET WT 3.53 oz (100 g)

For external use only

**Diclofenac Sodium Topical Gel, 1%**

**(NSAID) - arthritis pain reliever**

Original Prescription Strength

• For Daily Treatment of Arthritis Pain

• Anti-Inflammatory

**Pharmacist Choice**

Unvarnished Area

NDC 62379-401-01

**Use Enclosed Dosing Card to Measure a Dose**

Do not use if safety seal on tube nozzle is broken or missing.

Read product User Guide before use (not actual size)

Not for immediate pain relief

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

For arthritis pain relief

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.

**Drug Facts**

**Active ingredient** Diclofenac Sodium (NSAID) 1% (nonsteroidal anti-inflammatory drug)

**Purpose** Arthritis pain reliever

**Uses**

- for the temporary relief of arthritis pain ONLY in following areas:
  - hand, wrist, elbow (upper body areas)
  - foot, ankle, knee (lower body areas)
- this product may only be used 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
- rash
- facial swelling
- shock
- skin redness
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Drug Facts (continued)**

**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 thinner (anticoagulant) or steroid drug
- use 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.

↑ LIFT HERE

↓ LIFT FLAP FOR IMPORTANT DIRECTIONS & WARNINGS

**Drug Facts (continued)**

**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 disease, 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.

**Drug Facts (continued)**

**Ask a doctor or pharmacist before use if you are**

- taking any other drug
- under a doctor's care for any serious condition

**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
  - vomit blood
  - have bloody or black stools
- you 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

**Carton Label - 100 g**

**NDC 62379-401-02**

**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 (100g)

NDC 62379-0401-02

# Diclofenac Sodium Topical Gel, 1%

Pharmacist<sup>TM</sup>  
Choice

(NSAID) - arthritis pain reliever

NET WT 3.53 oz (100 g)

To open tube: Unscrew cap and open the seal that covers the tube opening by using the spiked top of the cap. Firmly press the cap to remove the safety seal.

This tube does not contain full product information. Retain outer carton, dosing card and User Guide for full product uses, directions and warnings.

Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.

## 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.

**If pregnant or breast-feeding,** 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.

**Keep out of reach of children.**

Store at 20-25°C (68-77°F). Keep from freezing.

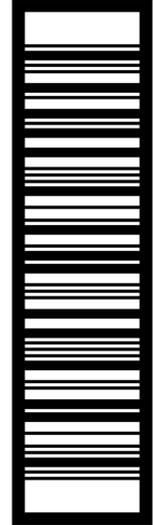
## Made in India

Code : GO/DRUGS/361

For lot number and expiration date, see crimp of tube or carton.

## Manufactured for:

 Simple Diagnostics  
PO Box 128  
Williston Park, NY 11596, USA  
Tel: 877-342-2385  
www.SimpleDiagnostics.com



**Diclofenac Sodium Topical Gel, 1% - 150 gm**

**Net Wt 5.29 oz (150g)**

**Tube Label- 150 g**

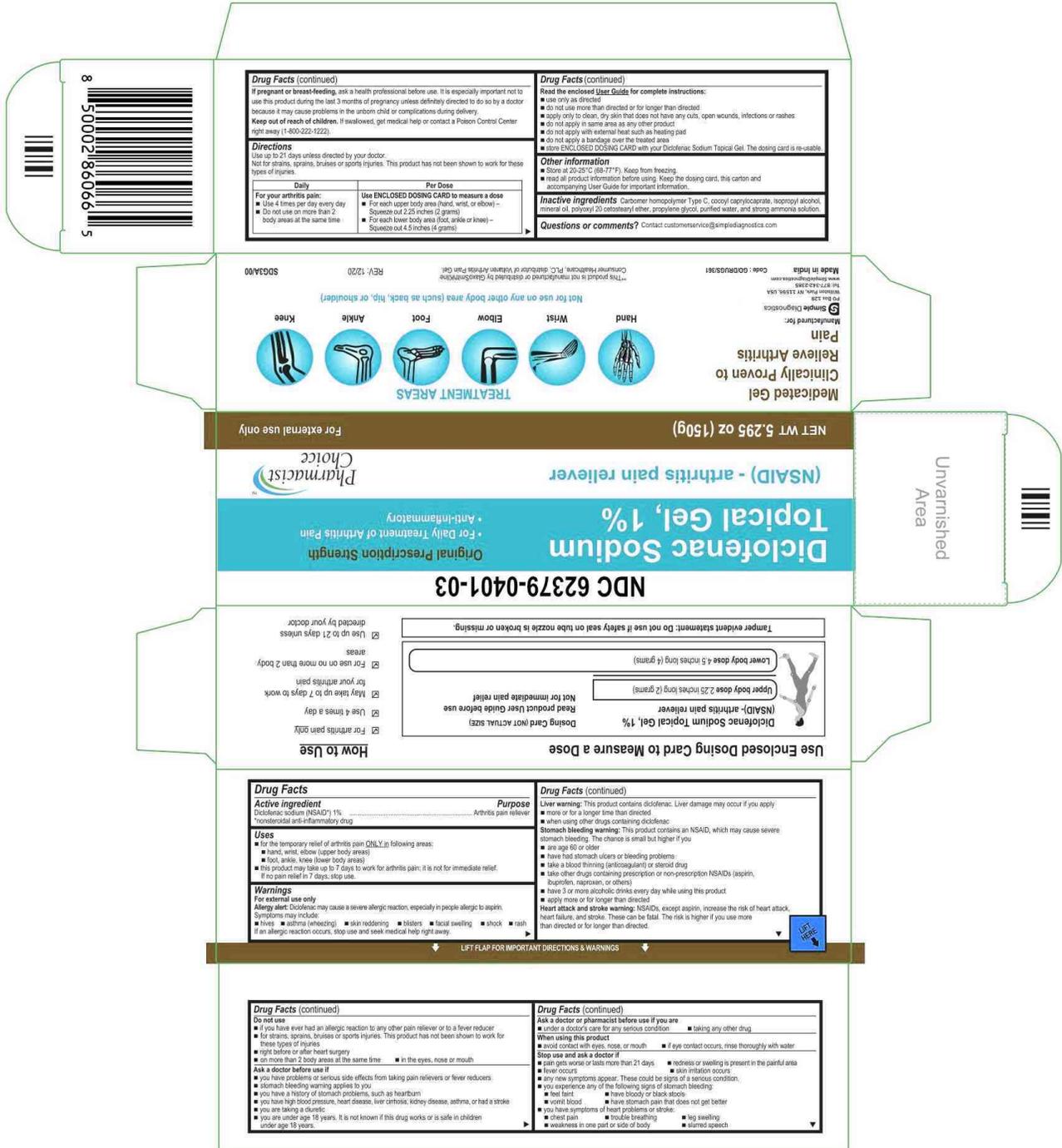
**NDC 62379-401-03**

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

**For external use only**

For daily Treatment of Arthritis Pain Anti-Inflammatory



**Carton Label - 150 g**

**NDC 62379-401-04**

Diclofenac Sodium Topical Gel, 1%

(NSAID)- Arthritis pain reliever

For daily Treatment of Arthritis Pain Anti-Inflammatory

Compare to the active ingredient in Voltaren Arthritis Pain Gel\*\*

**For external use only**

**For daily Treatment of Arthritis Pain Anti-Inflammatory**

**NDC 62379-0401-04**

**Diclofenac Sodium  
Topical Gel, 1%**

**Pharmacist  
Choice**

**(NSAID) - arthritis pain reliever**

**NET WT 5.295 oz (150g)**

To open tube: Unscrew cap and open the seal that covers the tube opening by using the spiked top of the cap. Firmly press the cap to remove the safety seal.

This tube does not contain full product information. Retain outer carton, dosing card and User Guide for full product uses, directions and warnings.

Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.

**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.

**If pregnant or breast-feeding,** 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.

**Keep out of reach of children.**

Store at 20-25°C (68-77°F). Keep from freezing.

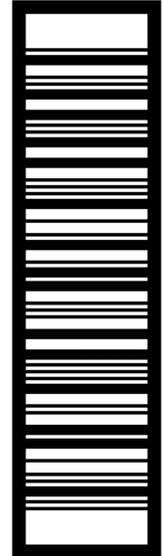
**Made in India**

Code : GO/DRUGS/361

For lot number and expiration date, see crimp of tube or carton.

**Manufactured for:**

 **Simple Diagnostics**  
PO Box 128  
Williston Park, NY 11596, USA  
Tel: 877-342-2385  
www.SimpleDiagnostics.com



**Dosing Card -Diclofenac Sodium Topical Gel, 1% (NSAID)- Arthritis pain reliever**

**Diclofenac Sodium Topical Gel, 1%**

**(NSAID)- Arthritis pain reliever**

Upper body dose 2.25 inches long (2 grams)

Lower body dose 4.5 inches long (4 grams)

**Dosing Card**

**Read product User Guide before use Not for immediate pain relief**

# Diclofenac Sodium Topical Gel, 1% (NSAID)- arthritis pain reliever

## Dosing Card

EDS0/00

Upper body dose 2.25 inches long (2 grams)

Read product User Guide before use  
Not for immediate pain relief

Lower body dose 4.5 inches long (4 grams)

### DICLOFENAC SODIUM

diclofenac sodium topical gel, 1% gel

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62379-401
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:14408QL0L1)	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: YRC528SWUY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
AMMONIA (UNII: 5138Q19F1X)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62379-401-02	1 in 1 CARTON	03/13/2024	
1	NDC:62379-401-01	100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:62379-401-04	1 in 1 CARTON	03/13/2024	
2	NDC:62379-401-03	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	ANDA210986	03/13/2024	

**Labeler** - Simple Diagnostics (004135503)

**Registrant** - Simple Diagnostics (004135503)

Revised: 3/2024

Simple Diagnostics