

**VOLTAREN ARTHRITIS PAIN- diclofenac sodium gel**

**VOLTAREN ARTHRITIS PAIN- diclofenac sodium**

**Haleon US Holdings LLC**

-----

## ***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.**

***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  |
|--|---|
| <b>For your arthritis pain:</b> <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> | <b>Use ENCLOSED DOSING CARD to measure a dose</b> <ul style="list-style-type: none"> <li>• • For each upper body area (hand, wrist, or elbow) –<br/>Squeeze out 2.25 inches (2 grams)</li> <li>• • For each lower body area (foot, ankle or knee) –<br/>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 Voltaren Arthritis Pain. The dosing card is re-usable.

***Other information***

- 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.

### ***Inactive ingredients***

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

### ***Questions or comments?***

**1-855-297-3031 [www.voltarengel.com](http://www.voltarengel.com)**

### **Additional Information**

#### **ORIGINAL PRESCRIPTION STRENGTH**

#### **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)

#### **TREATMENT AREAS**

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

#### **Voltaren ARTHRITIS PAIN**

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

### **Principal Display Panel**

**NDC 0067-8152-02**

**Voltaren**

**ARTHRITIS PAIN**

diclofenac sodium topical gel, 1% (NSAID) - arthritis pain reliever

Anti-Inflammatory

For Daily Treatment of Arthritis Pain

**For external use only**

**NET WT 1.76 oz (50 g)**

**1-855-297-3031**

Made in Canada

Distributed by: GSK Consumer Healthcare, Warren, NJ 07059

Trademarks owned or licensed by GSK.

©2021 GSK or licensor.

30000000000042 Front Carton



**Principal Display Panel**

**ORIGINAL PRESCRIPTION STRENGTH**

**Voltaren**

**ARTHRITIS PAIN**

**diclofenac sodium topical gel, 1% (NSAID)- arthritis pain reliever**

**ANTI-INFLAMMATORY**

**For Daily Treatment of Arthritis Pain**

**Medicated Gel Clinically Proven to Relieve Arthritis Pain**

**NEW FLIP TOP CAP\***

**\*Cap for 150 g only**

**For external use only**

## **TREATMENT AREAS**

- **Hand Wrist Elbow Foot Ankle Knee**
- Not for use on any other body area (such as back, hip, or shoulder)
- **Screw Cap Tamper evident statement: Do not use if safety seal on tube nozzle is broken or missing.**
- **Flip Cap Tamper evident statement: Do not use if plastic safety seals on sides of cap are broken or missing.**
- **1-855-297-3031**
- Made in India
- Distributed by: Haleon, Warren, NJ 07059
- Trademarks are owned by or licensed to the Haleon group of companies.
- @2023 Haleon group of companies or its licensor.
- 204419 Carton



## **VOLTAREN ARTHRITIS PAIN**

diclofenac sodium gel

### **Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0067-8152

|                         |         |
|-------------------------|---------|
| 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)   |          |

**Packaging**

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0067-8152-01 | 1 in 1 CARTON  | 05/13/2020           |                    |
| 1 |                  | 20 g in 1 TUBE; Type 1: Convenience Kit of Co-Package  |                      |                    |
| 2 | NDC:0067-8152-02 | 1 in 1 CARTON  | 05/13/2020           |                    |
| 2 |                  | 50 g in 1 TUBE; Type 1: Convenience Kit of Co-Package  |                      |                    |
| 3 | NDC:0067-8152-03 | 1 in 1 CARTON  | 05/13/2020           |                    |
| 3 |                  | 100 g in 1 TUBE; Type 1: Convenience Kit of Co-Package |                      |                    |
| 4 | NDC:0067-8152-04 | 1 in 1 CARTON  | 05/13/2020           |                    |
| 4 |                  | 150 g in 1 TUBE; Type 1: Convenience Kit of Co-Package |                      |                    |
| 5 | NDC:0067-8152-05 | 3 in 1 CARTON  | 09/01/2020           | 09/02/2020         |
| 5 |                  | 150 g in 1 TUBE; Type 1: Convenience Kit of Co-Package |                      |                    |
| 6 | NDC:0067-8152-08 | 2 in 1 CARTON  | 05/31/2021           |                    |
| 6 |                  | 100 g in 1 TUBE; Type 0: Not a Combination Product     |                      |                    |
| 7 | NDC:0067-8152-09 | 1 in 1 CARTON  | 05/31/2021           |                    |
| 7 |                  | 20 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 |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA022122                                | 05/13/2020           |                    |

## VOLTAREN ARTHRITIS PAIN

diclofenac sodium kit

### Product Information

|              |                |                    |               |
|--------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0067-8153 |
|--------------|----------------|--------------------|---------------|

### Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0067-8153-01 | 1 in 1 CARTON; Type 0: Not a Combination Product | 05/13/2020           |                    |

### Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 2 TUBE           | 300 g                  |
| Part 2 | 1 TUBE           | 50 g                   |

## Part 1 of 2

## VOLTAREN ARTHRITIS PAIN

diclofenac sodium gel

### Product Information

|                         |         |
|-------------------------|---------|
| 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) |          |



|   |  |
|---|--|
| <b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)         |  |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)             |  |
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)                   |  |
| <b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY) |  |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)              |  |
| <b>WATER</b> (UNII: 059QF0KO0R)                         |  |

## Packaging

| # | Item Code | Package Description                                | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 |           | 2 in 1 KIT   |                      |                    |
| 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 |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA022122                                | 05/13/2020           |                    |

## Part 2 of 2

## VOLTAREN ARTHRITIS PAIN

diclofenac sodium gel

## Product Information

|                                |         |
|--------------------------------|---------|
| <b>Route of Administration</b> | TOPICAL |
|--------------------------------|---------|

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| <b>DICLOFENAC SODIUM</b> (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1) | DICLOFENAC SODIUM | 10 mg in 1 g |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>AMMONIA</b> (UNII: 5138Q19F1X)   |          |
| <b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E) |          |
| <b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)   |          |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)   |          |
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)   |          |
| <b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)                                   |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)  |          |
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |

### Packaging

| # | Item Code | Package Description                               | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 |           | 1 in 1 KIT  |                      |                    |
| 1 |           | 50 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 |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA022122                                | 05/13/2020           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA022122                                | 05/13/2020           |                    |

**Labeler** - Haleon US Holdings LLC (079944263)

Revised: 3/2024

Haleon US Holdings LLC