

DICLOFENAC SODIUM- diclofenac sodium topical gel, 1% gel
Encube Ethicals Private Limited

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.

| Daily | Per Dose |
|---|---|
| <p>For your arthritis pain:</p> <ul style="list-style-type: none"> • Use 4 times per day every day • Do not use on more than 2 body areas at the same time | <p>Use ENCLOSED DOSING CARD to measure a dose</p> <ul style="list-style-type: none"> • 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% 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 caprylocaprates, isopropyl alcohol, mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, strong ammonia solution.

Question and comments 1-833-285-4151

Diclofenac Sodium Topical Gel, 1% -20 gm

Carton Label - 20 g

NDC 21922-044-25

ORIGINAL PRESCRIPTION STRENGTH

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

Net Wt 0.7 oz (20g)

NDC 21922-044-25

Encube

Diclofenac Sodium Topical Gel, 1%

(NSAID) - arthritis pain reliever

NET WT 0.7 oz (20 g)

To open tube: Unscrew cap and remove foil seal that covers the tube nozzle.

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.



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

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

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- 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 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.

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

Questions or comments? 1-833-285-4151

Manufactured by: **Encube Ethicals Pvt. Ltd.**
Plot No. C-1, Madkaim Industrial Estate, Madkaim,
Post: Mardol, Ponda, Goa - 403 404, India.
Distributed by: **Encube Ethicals, Inc.**
200 Meredith Avenue, Suite 101A Durham,
NC 27713 USA.

DOE1400
MFG. Lic. No.: 961



Diclofenac Sodium Topical Gel, 1% -50 gm

Carton Label - 50 g

NDC 21922-044-14

ORIGINAL PRESCRIPTION STRENGTH

Diclofenac Sodium Topical Gel, 1%

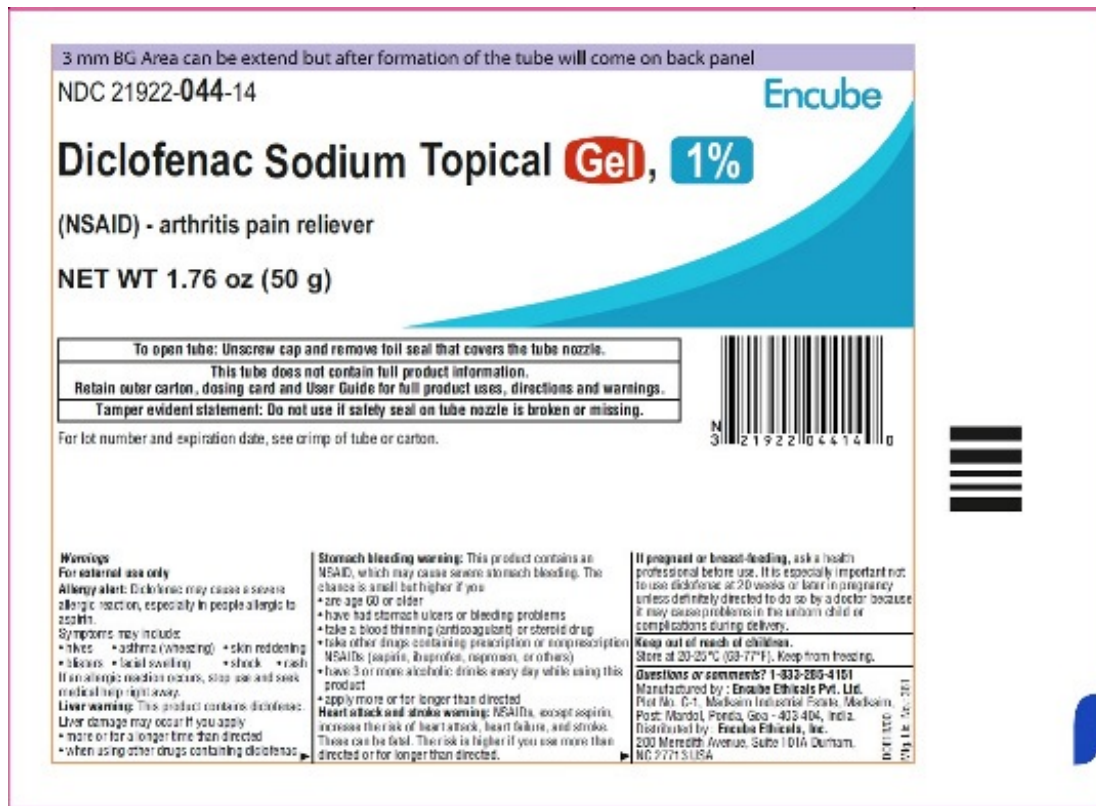
(NSAID)- Arthritis pain reliever

For daily Treatment of Arthritis Pain Anti-Inflammatory

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

For external use only

Net Wt 1.76 oz (50g)



Diclofenac Sodium Topical Gel, 1% -100 gm

Carton Label - 100 g

NDC 21922-044-09

ORIGINAL PRESCRIPTION STRENGTH

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

Net Wt 3.53 oz (100g)

Drug Facts (continued)

Do not use if you have had an allergic reaction to any other pain reliever or a fever reducer. It contains salicylates, which may cause allergic reactions in people who are allergic to aspirin. This product has not been shown to work for these types of injuries.

Warnings

For external use only. If you have had an allergic reaction to any other pain reliever or a fever reducer, do not use. If you have had an allergic reaction to any other pain reliever or a fever reducer, do not use. If you have had an allergic reaction to any other pain reliever or a fever reducer, do not use. If you have had an allergic reaction to any other pain reliever or a fever reducer, do not use.

Directions

Use up to 21 days unless directed by your doctor. This product has not been shown to work for these types of injuries.

Other information

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

Drug Facts (continued)

Do not use if you have had an allergic reaction to any other pain reliever or a fever reducer. It contains salicylates, which may cause allergic reactions in people who are allergic to aspirin. This product has not been shown to work for these types of injuries.

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Directions

Use up to 21 days unless directed by your doctor. This product has not been shown to work for these types of injuries.

Other information

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

Use Enclosed Dosing Card to Measure a Dose

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)

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

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

NDC 21922-044-09

ORIGINAL PRESCRIPTION STRENGTH



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**

NET WT 3.53 oz (100 g)

For external use only

Medicated Gel Clinically Proven to Relieve Arthritis Pain



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

Manufactured by: Encube Ethicals Pvt. Ltd., Plot No. C-1, Madkaim Industrial Estate, Madkaim, Post: Mardol, Ponda, Goa - 403 404, India.

Mfg. Lic. No.: 361

Distributed by: Encube Ethicals, Inc., 200 Meredith Avenue, Suite 101A Durham, NC 27713 USA

**This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, PLC, distributor of Voltaren Arthritis Pain Gel.

Drug Facts (continued)

Do not use if you have had an allergic reaction to any other pain reliever or a fever reducer. It contains salicylates, which may cause allergic reactions in people who are allergic to aspirin. This product has not been shown to work for these types of injuries.

Directions

Use up to 21 days unless directed by your doctor. This product has not been shown to work for these types of injuries.

Other information

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

Drug Facts (continued)

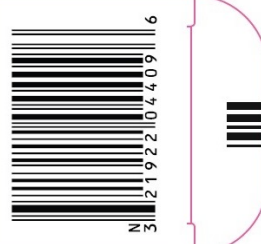
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Directions

Use up to 21 days unless directed by your doctor. This product has not been shown to work for these types of injuries.

Other information

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



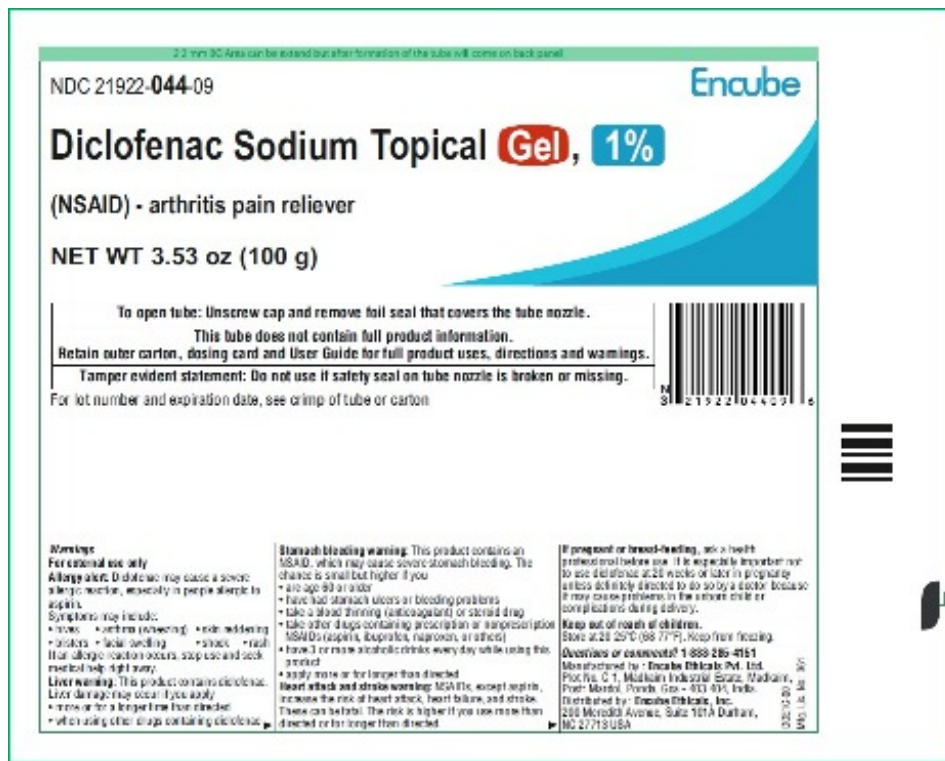
Container Label- 100 g

NDC 21922-044-09

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

For external use only

Net Wt 3.53 oz (100g)



Diclofenac Sodium Topical Gel, 1% - 150 gm

Carton Label - 150 g

NDC 21922-044-26

ORIGINAL PRESCRIPTION STRENGTH

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

Net Wt 5.29 oz (150g)

2.2 mm BG Area can be extend but after formation of the tube will come on back panel

NDC 21922-044-26

Encube

Diclofenac Sodium Topical Gel, 1%

(NSAID) - arthritis pain reliever

NET WT 5.29 oz (150 g)

To open tube: Unscrew cap and remove foil seal that covers the tube nozzle.

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.



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

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 redness
 - 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 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.

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

Questions or comments? 1-833-285-4151

Manufactured by: Encube Ethicals Pvt. Ltd., Plot No. C-1, Madkam Industrial Estate, Madkam, Post: Mandol, Ponda, Goa - 403 404, India.

Distributed by: Encube Ethicals, Inc., 200 Meredith Avenue, Suite 101A Durham, NC 27713 USA

ENC-19/20

Mfg. Lic. No.: 361

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:21922-044 |
| 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 |
|---|-----------------|
| 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:21922-044-25 | 1 in 1 CARTON | 02/01/2021 | |
| 1 | | 20 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:21922-044-14 | 1 in 1 CARTON | 02/01/2021 | |
| 2 | | 50 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:21922-044-09 | 1 in 1 CARTON | 08/11/2020 | |
| 3 | | 100 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:21922-044-26 | 1 in 1 CARTON | 02/01/2021 | |
| 4 | | 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 | 08/11/2020 | |

Labeler - Encube Ethicals Private Limited (915834105)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|---|
| Encube Ethicals Private Limited | | 725076298 | manufacture(21922-044) , analysis(21922-044) , pack(21922-044) , label(21922-044) |

Revised: 1/2025

Encube Ethicals Private Limited