

PAIN RELIEF GEL-ROLL ON- menthol gel
Trifecta Pharmaceuticals USA

Globe Pain Relief Gel Roll On

DRUG FACTS

Active Ingredient

Lidocaine 4%

Purpose

Topical Analgesic

Active Ingredient

Menthol 1%

Purpose

Topical Analgesic

Warnings

For external use only.

Flammable Keep away from excessive heat or flame.

Keep out of Reach of Children

If Swallowed, get medical help or contact a Poison Control Center right away

If Pregnant or breast feeding

If Pregnant or breast feeding as a doctor before use.

Directions

- Adults and children over 12 years: apply to the affected area not more than 3 to 4 times daily.
- Children 12 years or younger: ask a doctor
- After applying wash hands with soap and water

Indications and use

Temporarily relieves minor pain.

Other Information

- Store at 20° to 25°C (68° to 77°F)

Inactive Ingredient:

Aloe Vera Extract, Carbomer, Isopropyl Myristate, Lavender oil, Phenoxyethanol, Polysorbate 80, Propylene glycol, Tartaric Acid, Vitamin E, Water

Stop Use and Ask Doctor if

Stop use and ask doctor if

- Condition worsens
- severe burning sensation, redness, rash or irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury such as pain, swelling or blistering where the product was applied.

Questions?

Call 1-888-296-9067

Distributed By:

Trifecta Pharmaceuticals USA ®

101 NE Third Avenue, Suite 1500

Fort Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

SKU: 4092-FBA





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NDC: 69396-185-01

**FAST-ACTING
 PAIN
 RELIEF
 GEL-ROLL ON
 LIDOCAINE 4%
 +
 MENTHOL 1%**

***Compare to the active ingredients in Dr. Scholl's® Clinical Strength Pain Relief Roll-On**

Fast, Penetrating
 Pain Relief
 Targets Nerve Pain

Net Wt. 2.5 oz. (73mL)

ROLL ON



BACKACHE



STIFF NECK



SHOULDER PAIN



JOINT PAIN

LOT:
 EXP:



Drug Facts

| Active ingredients | Purpose |
|--------------------|--------------------|
| Lidocaine 4% | Topical anesthetic |
| Menthol 1% | Topical analgesic |

Use Temporarily relieves minor pain.

Warnings
For external use only.

Flammable. Keep away from fire or flame.

Do not use ■ if you have had an allergic reaction to lidocaine or other local anesthetics
 ■ do not use in large quantities, particularly over raw surfaces or blistered areas
 ■ for more than one week without consulting a doctor

When using this product ■ use only as directed. Read and follow all directions and warnings on this carton.
 ■ avoid contact with the eyes and mucous membranes
 ■ do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use
 ■ a transient burning sensation may occur upon application but generally disappears in several days

Stop use and ask a doctor if
 ■ condition worsens
 ■ severe burning sensation, redness, rash or irritation develops
 ■ symptoms persist for more than 7 days or clear up and occur again within a few days
 ■ you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding, ask a doctor before use.

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

Directions
 ■ **adults and children over 12 years:** apply to the affected area not more than 3 to 4 times daily
 ■ **children 12 years or younger:** ask a doctor
 ■ after applying, wash hands with soap and water

Other information Store at 20° - 25°C (68° - 77°F).

Inactive ingredients
 Aloe vera extract, Carbomer, Isopropyl myristate, Lavender oil, Phenoxylethanol, Polysorbate 80, Propylene glycol, Tartaric acid, Vitamin E, Water.

Questions? Call 1-888-296-9067

*This product is not manufactured or distributed by Scholl's Wellness Company LLC, the distributor of Dr. Scholl's® Clinical Strength Pain Relief Roll-On.

INNER BOTTLE

***Compare to the active ingredients in Dr. Scholl's® Clinical Strength Pain Relief Roll-On**

NDC: 69396-185-01

**FAST-ACTING
 PAIN
 RELIEF
 GEL-ROLL ON
 LIDOCAINE 4%
 +
 MENTHOL 1%**

Fast, Penetrating
 Pain Relief
 Targets Nerve Pain

Net Wt. 2.5 oz. (73mL)

ROLL ON

Drug Facts

| Active ingredients | Purpose |
|--------------------|--------------------|
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Stop use and ask a doctor if ■ condition worsens ■ severe burning sensation, redness, rash or irritation develops
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If pregnant or breast-feeding, ask a doctor before use.

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

Directions ■ **adults and children over 12 years:** apply to the affected area not more than 3 to 4 times daily. ■ **children 12 years or younger:** ask a doctor
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Other information Store at 20° - 25°C (68° - 77°F).

Inactive ingredients Aloe vera extract, Carbomer, Isopropyl myristate, Lavender oil, Phenoxylethanol, Polysorbate 80, Propylene glycol, Tartaric acid, Vitamin E, Water.

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SKU: 4092-FBA

Label



OUTSIDE BOX

| Drug Facts | |
|---|--------------------|
| Active ingredients | Purpose |
| Lidocaine 4% | Topical anesthetic |
| Menthol 1% | Topical analgesic |
| Use Temporarily relieves minor pain. | |
| Warnings | |
| For external use only. | |
| Flammable. Keep away from fire or flame. | |
| Do not use ■ If you have had an allergic reaction to lidocaine or other local anesthetics | |
| ■ do not use in large quantities, particularly over raw surfaces or blistered areas ■ for more than one week without consulting a doctor | |
| When using this product ■ use only as directed. Read and follow all directions and warnings on this label. | |
| ■ avoid contact with the eyes and mucous membranes; ■ do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use ■ a transient burning sensation may occur upon application but generally disappears in several days | |
| Stop use and ask a doctor if ■ condition worsens ■ severe burning sensation, redness, rash or irritation develops | |
| ■ symptoms persist for more than 7 days or clear up and occur again within a few days | |
| ■ you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied | |
| If pregnant or breast-feeding, ask a doctor before use. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions ■ adults and children over 12 years: apply to the affected area not more than 3 to 4 times daily ■ children 12 years or younger: ask a doctor | |
| ■ after applying, wash hands with soap and water | |
| Other information Store at 20° - 25°C (68° - 77°F). | |
| Inactive ingredients Aloe vera extract, Carbomer, Isopropyl myristate, Lavender oil, Phenoxyethanol, Polysorbate 80, Propylene glycol, Tartaric acid, Vitamin E, Water. | |
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PAIN RELIEF GEL-ROLL ON

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69396-185 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 40 g in 1 L |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 10 g in 1 L |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| TARTARIC ACID (UNII: W4888I119H) | |
| LAVENDER OIL (UNII: ZBP1YXW0H8) | |

| | |
|---|--|
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| WATER (UNII: 059QF0KO0R) | |
| ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB) | |
| CARBOMER (UNII: 0A5MM307FC) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69396-185-01 | 1 in 1 BOX | 04/30/2026 | |
| 1 | | 0.073 L in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:69396-185-03 | 3 in 1 BOX | 04/30/2026 | |
| 2 | | 0.073 L in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017 | 04/27/2026 | |

Labeler - Trifecta Pharmaceuticals USA (079424163)

Revised: 5/2026

Trifecta Pharmaceuticals USA