

PAIN RELIEF GEL ROLL ON- menthol gel
Trifecta Pharmaceuticals USA

Globe Pain Relief Gel-Roll On

DRUG FACTS

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Warnings

For external use only.

Flammable Keep away from excessive heat or open flames.

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 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily.
- Children under 2 years of age: ask a doctor
- Wash hands after use with cold water.

Indications and use

Temporarily relieves minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- bruises
- sprains

Other Information

-
- Store at 20° to 25°C (68° to 77°F)
- Store in cool dry place away from direct sunlight

Inactive Ingredient:

Alcohol, Aloe Vera extract, Arnica Montana Flower extract, Boswellia carteril resin extract, Camellia sinesis leaf extract, Camphor, Carbomer, FD&C Blue 1, FD&C Yellow 5, Glycerin, Ilex paraguariensis leaf extract, Isopropyl myristate, Silica, Triethanolamine, Vitamin E, Water.

Stop Use and Ask Doctor if

Stop use and ask doctor if

- you experience pain, swelling or blistering of the skin
- if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days
- arthritic pain persists for more than 10 days or redness is present, or in conditions affecting children under 12 years of age.

Questions?

Call 1-888-296-9067

Distributed By:

Trifecta Pharmaceuticals USA ®

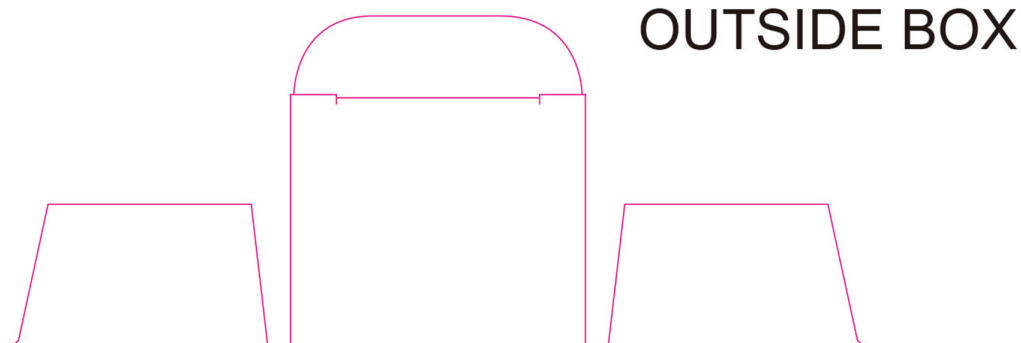
101 NE Third Avenue, Suite 1500

Fort Lauderdale, FL. 33301 USA

www.trifecta-pharma.com


SKU: 4091-FBA

Label





INNER BOTTLE

<p>*Compare to the active ingredients in Biofreeze*</p> <p>NDC: 69396-184-01</p> 		 <p>8 50058 16150 1</p>			
<p>Pain Relief Gel-Roll On</p> <p>MENTHOL 4%</p> <ul style="list-style-type: none"> Fast Acting, Long Lasting Targeted Cold Therapy Pain Relief <p>Net Wt. 2.5 oz. [74ml]</p> <p>TOPICAL PAIN RELIEF</p>					
<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Menthol 5%</td> <td>Topical Anesthetic</td> </tr> </tbody> </table> <p>Use Temporarily relieves minor aches and pains of muscles and joints associated with:</p> <ul style="list-style-type: none"> simple backache arthritis stains bruises sprains <p>Warnings</p> <p>For external use only.</p> <p>Flammable. Keep away from excessive heat or open flame.</p> <p>When using this product</p> <ul style="list-style-type: none"> use only as directed avoid contact with the eyes or mucous membranes do not apply to wounds or damaged skin do not apply to irritated skin or if excessive irritation develops do not bandage tightly or use with heating pad or device <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience pain, swelling or blistering of the skin condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days arthritis pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age <p>If pregnant or breast-feeding, ask a doctor before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily children under 2 years of age: ask a doctor wash hands after use with cool water <p>Other information</p> <ul style="list-style-type: none"> store at 20° - 25°C (68° - 77°F) store in a cool dry place away from direct sunlight <p>Inactive ingredients Alcohol, Aloe vera extract, Arnica montana flower extract, Boswellia carteri resin extract, Camphor, Carbomer, FD&C Blue 1, FD&C Yellow 5, Glycerin, Ilex paraguariensis leaf extract, Isopropyl myristate, Silica, Triethanolamine, Vitamin E, Water.</p> <p>Questions? Call 1-888-296-9067</p> <p><small>*This product is not manufactured or distributed by RB Health US the distributor of Biofreeze*</small></p>		Active ingredient	Purpose	Menthol 5%	Topical Anesthetic
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Menthol 5%	Topical Anesthetic				
<p>Distributed by:</p> <p>Trifecta Pharmaceuticals USA* 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA www.trifecta-pharma.com</p> <p>SKU: 4091-FBA</p>					



OUTSIDE BOX

PAIN RELIEF GEL ROLL ON

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-184
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SILICA (UNII: ETJ7Z6XBU4)	
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
CAMELLIA SINENSIS LEAF OIL (UNII: VC855RRT77)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
FRANKINCENSE (UNII: R9XLF1R1VM)	
CARBOMER (UNII: 0A5MM307FC)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-184-01	1 in 1 BOX	04/30/2026	
1		0.074 L in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69396-184-03	3 in 1 BOX	04/30/2026	
2		0.074 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: 4/2026

Trifecta Pharmaceuticals USA