

**MUSCLE RUB CREAM- menthol 10%, methyl salicylate 15% cream
Trifecta Pharmaceuticals USA, LLC.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Muscle Rub Cream

Drug Facts

Active Ingredient

Menthol 10%

Active Ingredient

Methyl Salicylate 15%

Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

Warnings

For external use only

Do not use:

- On wounds or damaged, broken, (open) or irritated skin
- With a heating pad

Ask a doctor before use if you are pregnant or breast feeding.

When using this product

- Avoid contact with eyes or mucous membrane
- Do not bandage tightly

Stop Use and ask a doctor

- Conditions worsens or does not improve within 7 days
- Symptoms clear up and occur again within a few days
- Excessive skin irritation develops

A temporary burning sensation may occur upon application, but generally disappears in a few days

Keep out of the reach of Children

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

- Adults and children 12 years of age or older. Apply to the affected area not more than 3 to 4 times daily.

Children under 12 years of age. consult a doctor

- Unless treating hands, wash hands thoroughly with soap and water immediately after use.

Other Information

- Store at controlled room temperature 20°-25°C (68°-77°F)

Questions ? Call 1-888-296-9067

Inactive Ingredients

Carbomer 940, Cetyl alcohol, Glycerol, Glyceryl monostearate, Methylparaben, Polysorbate 80, Propylparaben, Purified Water, Stearic acid, Trolamine

Distributed By

Trifecta Pharmaceuticals USA, LLC.

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301

www.trifecta-pharma.com

Packaging



10% MENTHOL • 15% METHYL SALICYLATE

Net Wt. 0.5 oz (15g)

TOPICAL ANALGESIC



0 40232 45504 9



www.trileta-pharma.com

Product of PFC
101 NE Third Avenue, Suite 1500
Lauderdale, FL 33301 USA

Distributed by:
Trileta Pharmaceuticals USA



LOT:
EXP: 4/2019

DRUG FACTS	<p>Active ingredient Menthol 10% Methyl Salicylate 15% Topical Analgesic</p> <p>Purpose Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p>
Directions	<p>• Adults and children 12 years of age or older: Apply to the affected area not more than 3 to 4 times daily. Children under 12 years of age: consult a doctor. Unless treating hands, wash hands thoroughly with soap and water immediately after use.</p>
Other information	<p>• Store at controlled room temperature, 20° - 25°C (68° - 77°F).</p>
Active ingredients	<p>Carbonate S40, Cetyl alcohol, Ethylalcohol, Glycerol, Inositol, Polybutene 80, Purified water, Stearic acid, Triolein</p>
Questions?	<p>Call 1-888-296-9067</p>

100% GUARANTEED

Muscle Rub Cream 10% MENTHOL • 15% METHYL SALICYLATE

INNER TUBE

NDC: 69396-024-05



Muscle Rub Cream

10% MENTHOL • 15% METHYL SALICYLATE

Net Wt. 0.5 oz (15g) **TOPICAL ANALGESIC**

<p>Active ingredient Menthol 10% Methyl Salicylate 15%</p> <p>Purpose Topical Analgesic Topical Analgesic</p> <p>Uses: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.</p> <p>Warning: For external use only. Do not use: • On wounds or damaged, broken, (open) or irritated skin. • With a heating pad. Ask a doctor before use if you have pregnancy or breast feeding.</p> <p>When using this product: • Avoid contact with eyes or mucous membrane. • Do not bandage tightly. Stop use and ask a doctor if: • Condition worsens or does not improve within 7 days. • Symptoms clear up and occur again within a few days. • Excessive skin irritation develops.</p>	<p>A temporary burning sensation may occur upon application, but generally disappears in a few days.</p> <p>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions: • Adults and children 12 years of age or older: Apply to the affected area not more than 3 to 4 times daily. Children under 12 years of age: consult a doctor. • Unless treating hands, wash hands thoroughly with soap and water immediately after use.</p> <p>Other information: • Store at controlled room temperature 20° - 25°C (68° - 77°F).</p> <p>Inactive ingredients: Carbonate S40, Cetyl alcohol, Ethylalcohol, Glycerol, Glyceryl monostearate, Polybutene 80, Purified water, Stearic acid, Triolein</p> <p>Questions? Call 1-888-296-9067</p>
--	--

Distributed by: Trileta Pharmaceuticals USA
101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Product of PFC | www.trileta-pharma.com

MUSCLE RUB CREAM

menthol 10%, methyl salicylate 15% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-024
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-024-05	1 in 1 BOX	12/29/2016	
1		15 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
OTC monograph not final	part348	12/29/2016	

Labeler - Trifecta Pharmaceuticals USA, LLC. (079424163)

Revised: 1/2023

Trifecta Pharmaceuticals USA, LLC.