

TOTAL MUSCLE RELIEF- menthol, camphor gel
Electrostim Medical Services Inc. d/b/a EMSI

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.

ACTIVE INGREDIENT

Menthol ---5.0%

PURPOSE

Cooling Pain Relief

USES

Temporary relief from minor aches and pains of sore muscles and joints associated with arthrilis
backaches strains sprains

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE; KEEP AWAY FROM EXCESSIVE HEAT OR OPEN FLAME.

Ask doctor before use if you have: Sensitive skin. When using this product: Avoid contact with the eyes or mucus membranes. Do not apply to wounds or damaged skin. Do not use with other ointments, creams, sprays or liniments. Do not apply to irritated skin or if excessive irritation develops. Do not bandage. Wash hand after use with cold water. Do not use heating pads or device. Store in a cool dry place.

Stop use and ask doctor if: condition worsens or if symptoms persist for more than 7 days or clear up and recur.

If pregnant or breast feeding: ask a health professional before use.

Keep out of reach of children: if accidentally ingested get medical help or contact Poison Control Center immediately.

DIRECTIONS

ADULT AND CHILDREN 2 YEARS OF AGE AND OLDER: RUB A THIN FILM OVER
AFFECTED AREAS NOT MORE THAN 4 TIMES DAILY. MASSAGE NOT NECESSARY.

CHILDREN UNDER 2 YEARS OF AGE: CONSULT PHYSICIAN.

INACTIVE INGREDIENTS

PURIFIED WATER, Extract of Aloe Vera, Witch Hazel, Water Cress and Rosemary, Isopropanol, Glycerin, Coconut Oil, Sweet Almond Oil, Emu Oil, Carbomer, Sodium Hydroxide, Silica, F. D. & C Yellow #5, F. D. & C Blue #1, DMDM Hydantoin

T M R

ADVANCED COLD THERAPY PAIN RELIEF

TOTAL MUSCLE RELIEF

For arthritis, neck & back pain, sore muscles & joints

3 fl oz (89 ml)

Drug Facts

Active Ingredient	Purpose
Menthol ---5.0%.....	Cooling Pain Relief

Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis backaches strains sprains

Warnings: For external use only.

Flammable; Keep away from excessive heat or open flame.

Ask doctor before use if you have: Sensitive skin.

When using this product: Avoid contact with the eyes or mucus membranes. Do not apply to wounds or damaged skin. Do not use with other ointments, creams, sprays or liniments. Do not apply to irritated skin if excessive irritation develops. Do not bandage. Wash hand after use with cold water. Do not use heating pads or device. Store in a cool dry place.

Stop use and ask doctor if: condition worsens or if symptoms persist for more than 7 days or clear up and recur.

If pregnant or breast feeding: ask a health professional before use. Keep out of reach of children: if accidentally ingested get medical help or contact Poison Control Center immediately.

Directions:

Adult and children 2 years of age and older: Rub a thin film over affected areas not more than 4 four times daily. Massage not necessary.

Children under 2 years of age: Consult physician.

Inactive Ingredients: Purified water, Extract of Aloe Vera, Witch Hazel, Water Cress and Rosemary, Isopropanol, Glycerin, Coconut Oil, Sweet Almond Oil, Emu Oil, Carbomer, Sodium Hydroxide, Silica, F. D. & C Yellow #5, F. D.& C Blue #1, DMDM Hydantoin

TMR

P.O. Box 1548

Mango, Florida 33550

www.MyTMRStore.com

(800)588-8383



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ADVANCED COLD THERAPY PAIN RELIEF

TOTAL MUSCLE RELIEF

For arthritis, neck & back pain, sore muscles & joints

T M R

4 fl oz (89 ml)

Drug Facts

Active Ingredient	Purpose
Menthol ---5.0%.....	Cooling Pain Relief

Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis backaches strains sprains

Warnings: For external use only.

Flammable; Keep away from excessive heat or open flame.

Ask doctor before use if you have: Sensitive skin.

When using this product: Avoid contact with the eyes or mucus membranes. Do not apply to wounds or damaged skin. Do not use with other ointments, creams, sprays or liniments. Do not apply to irritated skin if excessive irritation develops. Do not bandage. Wash hand after use with cold water. Do not use heating pads or device. Store in a cool dry place.

Stop use and ask doctor if: condition worsens or if symptoms persist for more than 7 days or clear up and recur.

If pregnant or breast feeding: ask a health professional before use. Keep out of reach of children": if accidentally ingested get medical help or contact Poison Control Center immediately.

Directions:

Adult and children 2 years of age and older: Rub a thin film over affected areas not more than 4 four times daily. Massage not necessary.

Children under 2 years of age: Consult physician.

Inactive Ingredients: Purified water, Extract of Aloe Vera, Witch Hazel, Water Cress and Rosemary, Isopropanol, Glycerin, Coconut Oil, Sweet Almond Oil, Emu Oil, Carbomer, Sodium Hydroxide, Silica, F. D. & C Yellow #5, F. D.& C Blue #1, DMDM Hydantoin

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ADVANCED COLD THERAPY PAIN RELIEF

TOTAL MUSCLE RELIEF

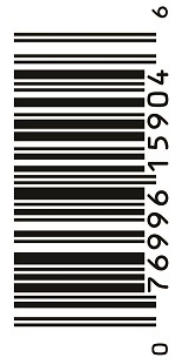
For arthritis, neck & back pain, sore muscles & joints

TMR

16 fl oz (473 ml)

Drug Facts	
Active Ingredient	Purpose
Menthol ---5.0%.....	Cooling Pain Relief
Uses: Temporary relief from minor aches and pains of sore muscles and joints associated with arthritis backaches strains sprains	
Warnings: For external use only. Flammable; Keep away from excessive heat or open flame.	
Ask doctor before use if you have: Sensitive skin. When using this product: Avoid contact with the eyes or mucus membranes. Do not apply to wounds or damaged skin. Do not use with other ointments, creams, sprays or liniments. Do not apply to irritated skin of if excessive irritation develops. Do not bandage. Wash hand after use with cold water. Do not use heating pads or device. Store in a cool dry place.	
Stop use and ask doctor if: condition worsens or if symptoms persist for more than 7 days or clear up and recur.	
If pregnant or breast feeding: ask a health professional before use. Keep out of reach of children": if accidentally ingested get medical help or contact Poison Control Center immediately.	
Directions: Adult and children 2 years of age and older: Rub a thin film over affected areas not more than 4 four times daily. Massage not necessary. Children under 2 years of age: Consult physician.	
Inactive Ingredients: Purified water, Extract of Aloe Vera, Witch Hazel, Water Cress and Rosemary, Isopropanol, Glycerin, Coconut Oil, Sweet Almond Oil, Emu Oil, Carbomer, Sodium Hydroxide, Silica, F. D. & C Yellow #5, F. D.& C Blue #1, DMDM Hydantoin	

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TOTAL MUSCLE RELIEF			
menthol, camphor gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50130-108
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.0 g in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
WITCH HAZEL (UNII: 101I4J0U34)			
WATERCRESS (UNII: K5877MW0LE)			
ROSEMARY (UNII: IJ67X351P9)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
GLYCERIN (UNII: PDC6A3C0OX)			

COCONUT OIL (UNII: Q9L0O73W7L)	
ALMOND OIL (UNII: 66YXD4DKO9)	
EMU OIL (UNII: 344821WD61)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 130-108-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2019	
2	NDC:50 130-108-13	89 mL in 1 TUBE; Type 0: Not a Combination Product	02/16/2019	
3	NDC:50 130-108-23	89 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	02/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/16/2019	

Labeler - Electrostim Medical Services Inc. d/b/a EMSI (932471881)

Establishment

Name	Address	ID/FEI	Business Operations
DIVERSIFIED MANUFACTURING CORP		185073996	manufacture(50 130-108)