POLAR FROST COLD- menthol gel
Mettler Electronics Corp.

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.

Polar® Frost Cold Gel

Drug Facts

Active Ingredient

Menthol 4%

Purpose

cooling pain relief

Uses

Provides cooling pain relief of minor aches and pains of muscles and joints associated with simple back-ache, arthritis, strains, bruises and sprains.

Warnings

For external use only

Do not use on wounds or damaged skin

When using this product

- avoid contact with eyes
- avoid contact with mucous membranes
- do not bandage

- If rash or irritation occurs, discontinue use.
- The application of external heat, such as an electric heating pad, may result in excessive skin irritation or skin burn.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

- Keep out of reach of children.

Directions

- Adults and children 2 years of age and older:
- Apply a thin layer to the affected area.
- Make a second application in 5 minutes.
- Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Do not use, consult a doctor.

Inactive Ingredients

Water, Alcohol, Eucalyptus Globulus Leaf Oil, Carbomer, Aloe Barbadensis Extract, Propylene

Glycol, Triethanolamine, Methylparaben, Silica, Propylparaben, Cl 42090 (FD&C Blue No. 1)

PRINCIPAL DISPLAY PANEL - 150 ml Tube Label

With Aloe Vera

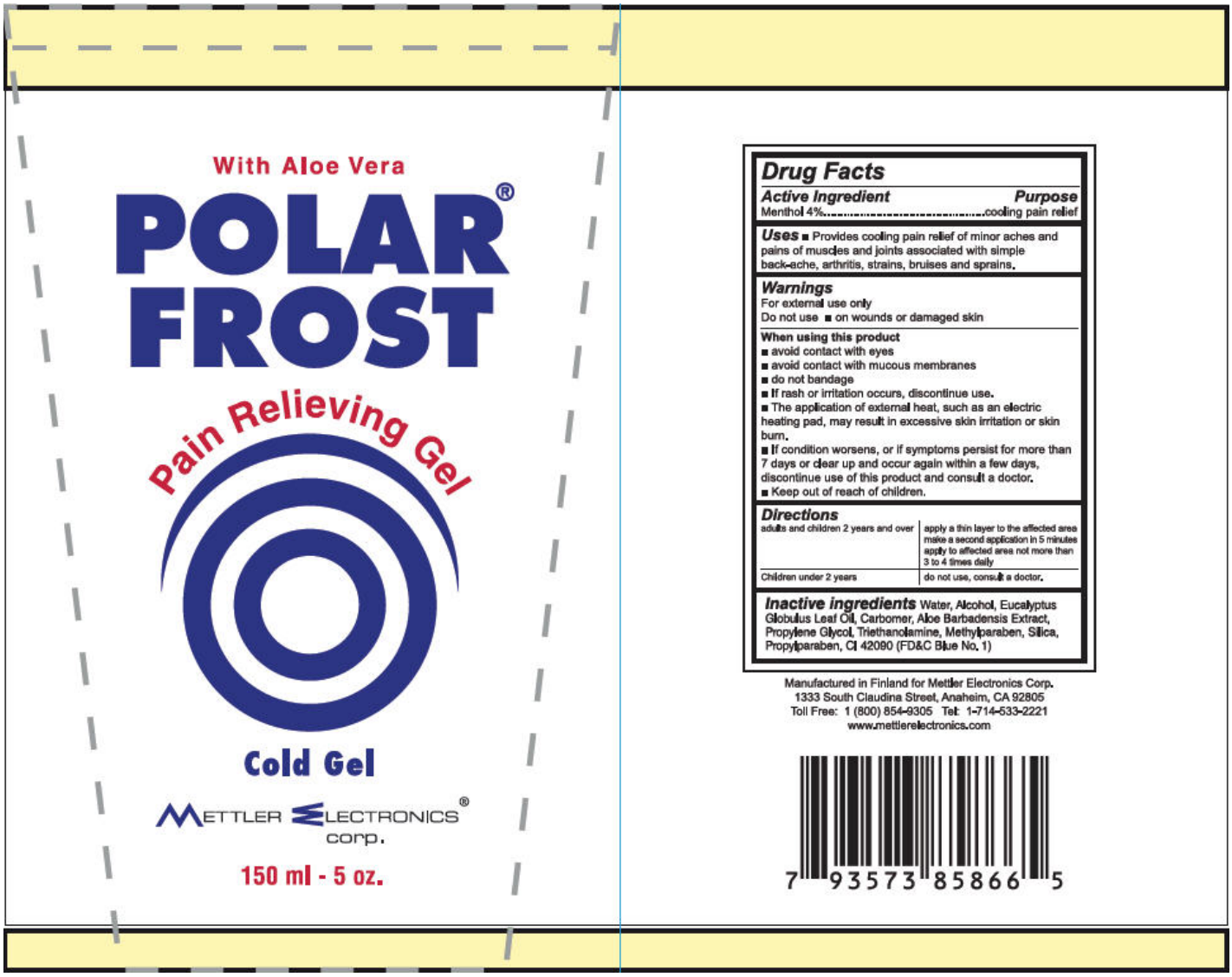
POLAR®
FROST

Pain Relieving Gel

Cold Gel

METTLER ELECTRONICS®
corp.

150 ml - 5 oz.



POLAR FROST COLD

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67138-533
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Alcohol (UNII: 3K9958V90M)	
Eucalyptus Oil (UNII: 2R04ONI662)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Trolamine (UNII: 9O3K93S3TK)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Carbomer Homopolymer Type C (Allyl Pentaerythritol Crosslinked) (UNII: 4Q93RCW27E)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67138-533-15	150 mL in 1 TUBE		
2	NDC:67138-533-75	75 mL in 1 BOTTLE, WITH APPLICATOR		
3	NDC:67138-533-50	500 mL in 1 BOTTLE, PUMP		
4	NDC:67138-533-05	5.43 mL in 1 POUCH		
5	NDC:67138-533-64	3785 mL in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	11/11/2002	

Labeler - Mettler Electronics Corp. (008513913)

Establishment

Name	Address	ID/FEI	Business Operations
Niva Medical Oy		651595779	MANUFACTURE(67138-533)