

THERAFREEZE - menthol gel
Astrum Pharma

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.

THERAFREEZE™

Drug Facts

Active Ingredients

Menthol USP 6%

Purpose

Pain Reliever

Uses

Temporary relief from minor aches and pains from sore muscles & joints associated with arthritis, backache, strains and sprains.

Warnings

For external use only.

Flammable: Keep away from excessive heat or open flame.

Ask a doctor before use if you have: sensitive skin.

When Using This Product:

- Avoid contact with eyes or mucous membrane.
- 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 tightly.
- Wash hands after use with cold water.
- Do not use with a heating pad or device.

Stop Use and Ask Doctor if

- conditions worsen.
- symptoms persist for more than 7 days.
- symptoms clear up and occur again within a few days.

If pregnant or breastfeeding:

Ask a health professional before use.

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

Directions

Adults and children 12 years of age and older: Apply on the affected areas not more than 4 times a day.

Children under 2 years of age: Consult physician.

Other information

Store in cool dry place.

Inactive ingredients:

Aloe Barbadosis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arctum Lappa (Burdock) Root Extract, Arnica Montana Extract, Boswellia Serrata Extract, C13-14 Isoparaffin, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Carbomer-940, Cetearyl Oliviate, Citrus Media Limonum (Essential Lemon) Oil, Ethylhexylglycerin, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Distillate, Helianthus Annuus (Sunflower) seed Oil, Ilex Paraguariensis Leaf (Yerba Mate') Extract, Laureth-7, Methylsulfonylmethane (MSM), PEG - 100 Stearate, Phenoxyethanol, Polyacrylmide, Polysorbate - 20, Propylene Glycol, Sorbitan Oliviate, Stearic Acid, Tocopheryl Acetate (Vitamin - E), Triethanolamine.

Questions or Comments? 1-800-590-3906

**For more information,
please visit our website
www.astrumpharma.com**

Manufactured in the USA

No Animal Testing

**Distributed and Marketed by:
Astrum Pharma, Jersey City,
NJ-07307**

Principal Display Panel

**SOOTHING PAIN RELIEF FROM ARTHRITIS, BACK PAIN,
SORE MUSCLES AND JOINTS**

Cool Therapy Pain Relieving Gel

THERAFREEZE™

Vanishing Scent • Natural Menthol • Paraben Free

NDC # 57329-010-01

16 FL OZ

473 ML

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Stop Use and Ask Doctor If:
- condition worsens - symptoms persist for more than 7 days
- symptoms clear up and reoccur within a few days

If pregnant or breastfeeding:
Ask a health professional before use.
Keep out of reach of children: If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions
Adults and children 2 years of age and older: Apply on the affected areas not more than 4 times a day
Children under 2 years of age: Consult physician

Other information:
Store in a cool dry place

Inactive Ingredients: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arctum Lappa (Burdock) Root Extract, Arnica Montana Extract, Boswellia Serrata Extract, C13-14 Isoparaffin, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Carbomer-940, Cetearyl Olivat, Citrus Medica Limonum (Essential Lemon) Oil, Ethylhexylglycerin, Glyceryl Stearate, Hamamelis Virginiana (Witch Hazel) Distillate, Helianthus Annuus (Sunflower) seed Oil, Ilex Paraguariensis Leaf (Yerba Mate) Extract, Laureth-7, Methylsulfonylmethane (MSM), PEG - 100 Stearate, Phenoxyethanol, Polyacrylamide, Polysorbate - 20, Propylene Glycol, Sorbitan Olivat, Stearic Acid, Tocopheryl Acetate (Vitamin - E), Triethanolamine

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Lot No.
Best By:



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No Animal Testing

Distributed & Marketed by:



Astrum Pharma, Jersey City, NJ - 07307

THERAFREEZE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57329-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	

ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
CITRUS LIMON FRUIT OIL (UNII: 0HNC1J1YED)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
WITCH HAZEL (UNII: 101I4J0U34)
SUNFLOWER OIL (UNII: 3W1JG795YI)
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)
LAURETH-7 (UNII: Z95S6G8201)
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SORBITAN OLIVATE (UNII: MDL271E3GR)
STEARIC ACID (UNII: 4ELV7Z65AP)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57329-010-01	473 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/08/2013	

Labeler - Astrum Pharma (026303692)

Revised: 8/2013

Astrum Pharma