

DUSEL COOL ARTHRITIS DEAD SEA SALT THERAPY- menthol cream
Nanovita One 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.

Dusel Cool Arthritis Dead Sea Salt Therapy

Drug Facts:

Active Ingredient:

Menthol 5.00%

Topical Analgesic

Indications:

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

Warnings:

- For external use only.
- Avoid contact with eyes.
- If symptoms persist for more than seven days, discontinue use and consult physician

Keep out of reach of children.

If swallowed, consult physician.

Do not apply

- to wounds or damaged skin.
- Do not bandage tightly.

If pregnant or breast feeding,

- contact physician prior to use.

Directions:

- Adults and children two-years of age or older: Apply to affected area not more than three to four times daily.
- Children under two-years of age: consult a physician.

Additional Information:

Store at room temperature.

Other Ingredients:

Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Ethylhexylglycerin, Glyceryl Stearate SE, Helianthus Annuus (Sunflower) Oil, Ilex

Paraguayensis (Yerba Mate') Extract, C13-14 Isoparaffin, Isopropyl Alcohol, Isopropyl Myristate, Maris Sal (Dead Sea) Salt, Phenoxyethanol, Laureth-7, Polyacrylamide, Stearic Acid.

Package Labeling:



Dead Sea Salt Therapy

enriched with Menthol 5ml

Distributed By: Nanovita One LLC 1420 Northbrook Dr. Box 3 Gardendale, AL 35068
 Nature. Science. Health. www.DuSel.com | (844) NAN-OVITA

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<p>Indications: For the temporary relief of minor aches and pains of the muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.</p>	<p>Additional Information: Store at room temperature.</p>
<p>Warnings: •For external use only. •Avoid contact with eyes. •If symptoms persist for more than seven days, discontinue use and consult physician. •Keep out of reach of children. If swallowed, consult physician. •Do not apply to wounds or damaged skin. •Do not bandage tightly. •If pregnant or breast feeding, contact physician prior to use.</p>	<p>Other Ingredients: Aloe Barbadosensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Arnica Montana Flower Extract, Ethylhexylglycerin, Glyceryl Stearate SE, Helianthus Annuus (Sunflower) Oil, Ilex Paraguayensis (Yerba Mate') Extract, C13-14 Isoparaffin, Isopropyl Alcohol, Isopropyl Myristate, Maris Sal (Dead Sea) Salt, Phenoxyethanol, Laureth-7, Polyacrylamide, Stearic Acid.</p>



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 menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70656-744	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	50 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
WATER (UNII: 059QF0KO0R)				
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)				
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)				
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
LAURETH-7 (UNII: Z95S6G8201)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70656-744-01	5 mL in 1 PACKET; Type 0: Not a Combination Product	04/26/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/26/2016		

Labeler - Nanovita One LLC (080217774)

Revised: 2/2017

Nanovita One LLC