

RELIEVE YOUR PAIN- menthol cream

SOLITEINT Kozmetikum gyarto es forgalmazo, termelo es kereskedelmi Korlatolt Felelossegu Tarsasag

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.

Asutra Relieve Your Pain

Active Ingredients

Menthol USP 10%

Purpose

Menthol USP 10%.....Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

Use only as directed. For external use only.

When using this product:

- avoid contact with eyes and mucous membranes
- do not apply to wounds or damaged skin
- do not bandage or use with a heating pad, other ointments, creams, sprays, or liniments.

Stop use and ask doctor if:

- condition worsens
- symptoms persist for more than 7 days, or clear up and reoccur again within a few days

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

Adults and children 2 years of age and older:

- Apply to affected area not more than 3 to 4 times daily.

Other Information

- Store in a cool, dry place.
- Avoid direct sunlight.
- Tamper-evident for your protection. Use only if safety seal is intact.
- Keep away from excessive heat or flame.

Inactive Ingredients

Aqua, Magnesium Chloride, Dimethyl Sulfone (Methylsulfonylmethane), Glyceryl Stearate SE, Cetearyl Alcohol, Sweet Almond Oil (*Prunus Amygdalus Dulcis*), Shea Butter (*Butyrospermum Parkii*), Cetareth-20, Glycerin, Pentylene Glycol, Undecane, Tocopheryl Acetate, Cetyl Palmitate, Arnica Montana Flower Extract, Tocopherol, Xanthan Gum, Tridecane, Sodium Chloride, Potassium Chloride, Magnesium Sulfate, Calcium Chloride, Ascorbyl Palmitate, Hydroxyacetophenone

Questions or Comments?

888-819-6472; Monday-Friday, 9am-5pm CT

Report any serious side effects to number above.

NDC 72683-005-01

Non-toxic

Paraben Free

Asutra*

Relieve

your

pain

10% Menthol

Pain Relief Cream

With Moisturizing

Magnesium and

Arnica Montana

Net Wt. 3.4 oz. | 96 g.

NDC
79283-000-01



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Drug Facts (continued)

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Listed with the FDA
Distributed by Asutra
4159 W. Montrose Ave.
Chicago, IL 60641

Manufactured by Wanadis Kft
Budapest, Hungary



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Peel

RELIEVE YOUR PAIN

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75249-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TRIDECANE (UNII: A3LZF0L939)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
UNDECANE (UNII: JV0QT00NUE)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
ALMOND OIL (UNII: 66YXD4DKO9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75249-005-01	96 g in 1 TUBE; Type 0: Not a Combination Product	04/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/29/2021	

Labeler - SOLITEINT Kozmetikum gyarto es forgalmazó, termelo es kereskedelmi Korlatolt Felelossegu Tarsasag (401476254)

Establishment

Name	Address	ID/FEI	Business Operations
SOLITEINT Kozmetikum gyarto es forgalmazo termelo es kereskedelmi Korlatolt Felelossegu Tarsasag		401476254	manufacture(75249-005)

Revised: 2/2022

SOLITEINT Kozmetikum gyarto es forgalmazo, termelo es kereskedelmi Korlatolt Felelossegu Tarsasag