

MELT PAIN AWAY- capsaicin 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.

Melt Pain Away (SOLITEINT)

Capsaicin .025%

Topical Analgesic

Temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

Use only as directed.

For external use only.

When using this product:

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask doctor if:

- condition worsens
- symptoms persist for more than 7 days, or clear up and reoccur again with a few days
- redness is present
- irritation develops.

If pregnant or breastfeeding, ask a health professional before use.

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

Adults and children over 18 years:

- Apply to affected area. Massage into the painful area until thoroughly absorbed. Repeat as necessary but no more than 3 to 4

times daily.

- Wash hands with soap and water after applying.

Children 18 years and younger:

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

Water, Magnesium Chloride, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Dimethyl Sulfone (MSM), Sodium Lactate, Glyceryl Stearate

Citrate, Cetyl Palmitate, Glycerin, Glyceryl Stearate, Polyglyceryl-3 Diisostearate, Pentylene Glycol, Undecane, Xanthan Gum, Magnesium Sulfate, Tridecane, Potassium Chloride, Sodium Chloride, Calcium Chloride, Tocopheryl Acetate (Vitamin E), Hydroxyacetophenone, Panthenol, Allantoin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Sodium Hydroxide, Cymbopogon Flexuosus (East-Indian Lemongrass) Oil* *Organic

888-819-6472; Monday–Friday, 9am–5pm CT
Report any serious side effects to number above.

***Production note: match color to ink drawdowns**



The image shows the packaging for Asutra Melt pain away. The background is a deep blue with a stylized, abstract illustration of a flower or plant in shades of purple and yellow. The text is arranged in a clean, modern layout. On the left side, there is a list of product details including NDC number, active ingredients, uses, warnings, directions, and inactive ingredients. On the right side, the brand name 'Asutra*' is at the top, followed by the product name 'Melt pain away' in large, bold, white letters. Below that, the active ingredient 'Capsaicin .025%' and the product type 'Pain Relief Cream' are listed. Further down, it says 'Revitalizing Magnesium Body Butter'. At the bottom right, the net weight is given as '0.067 oz. | 1.9 g.'.

NDC: 72683-003-02

Active Ingredients, Purpose
Capsaicin .025% (Topical Analgesic)

Uses
Temporarily relieves minor aches and pains of muscles and joints associated with: • arthritis • simple backache • strains • sprains • bruises

Warnings
Use only as directed. For external use only. When using this product: • avoid contact with eyes • do not apply to wounds or damaged skin • do not bandage tightly

Directions
Adults and children over 18 years: • Apply to affected area. Massage into the painful area until thoroughly absorbed. Repeat as necessary but no more than 3 to 4 times daily. • Wash hands with soap and water after applying. **Children 18 years and younger:** • Consult a doctor.

Inactive Ingredients: Water, Magnesium Chloride, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Dimethyl Sulfone (MSM), Sodium Lactate, Glyceryl Stearate Citrate, Cetyl Palmitate, Glycerin, Glyceryl Stearate, Polyglyceryl-3 Diisostearate, Pentylene Glycol, Undecane, Xanthan Gum, Magnesium Sulfate, Tridecane, Potassium Chloride, Sodium Chloride, Calcium Chloride, Tocopheryl Acetate (Vitamin E), Hydroxyacetophenone, Panthenol, Allantoin, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Sodium Hydroxide, Cymbopogon Flexuosus (East-Indian Lemongrass) Oil* *Organic

Learn more at asutra.com
Distributed by Asutra
4159 W. Montrose Ave.
Chicago, IL 60641 USA

Asutra*
**Melt
pain
away**

Capsaicin .025%
Pain Relief Cream

**Revitalizing
Magnesium Body Butter**

Net Wt. 0.067 oz. | 1.9 g.

MELT PAIN AWAY

capsaicin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75249-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
PANTHENOL (UNII: WV9CM0O67Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CYMOPOGON FLEXUOSUS LEAF (UNII: 7LJ4Y1UJG7)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
UNDECANE (UNII: JV0QT00NUE)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIDECANE (UNII: A3LZF0L939)	
POTASSIUM CHLORIDE (UNII: 660YQ98H0)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALMOND OIL (UNII: 66YXD4DKO9)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75249-003-01	200 g in 1 JAR; Type 0: Not a Combination Product	04/15/2020	
2	NDC:75249-003-02	1.9 g in 1 PACKET; Type 0: Not a Combination Product	04/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/15/2020	

Labeler - SOLITEINT Kozmetikum gyarto es forgalmazo 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(75249-003)

Revised: 4/2020 SOLITEINT Kozmetikum gyarto es forgalmazo termelo es kereskedelmi Korlatolt Felelossegu Tarsasag