

**RECOVERY ROLL-ON- menthol, camphor gel
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 Recovery Roll-On

Active Ingredients

Menthol 5%

Camphor 5%

Purpose

Menthol 5%.....Topical Analgesic

Camphor 5%.....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 tightly 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 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.

Directions

Adults and children 2 years of age and older:

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

Children under 2 years of age:

- Consult a doctor.

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

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Dimethyl Sulfone, Magnesium Chloride, Cetearyl Alcohol, Glyceryl Stearate, Polyglyceryl-6 Palmitate/Succinate, Glycerin, Hydroxyacetophenone, Tocopheryl Acetate, Xanthan Gum, Caprylyl Glycol, 1,2-Hexanediol, Acacia Senegal Gum, Pentaerythrityl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Magnesium Sulfate, Potassium Chloride, Sodium Chloride, Calcium Chloride

Questions or Comments?

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

NDC: 72683-008-01

Non-toxic

Paraben Free

Asutra*

Recovery Roll-On

5% Menthol + 5% Camphor

Pain Relief Gel

With Revitalizing Magnesium

1.7 fl. oz. | 50 ml.

NDC:
79687-008-01

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Drug Facts (continued)

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ANIMAL
WELFARE
FOUNDATION
FOR
VEGAN

Learn more at asutra.com



Pool

Glue area — does not print

Drug Facts (continued)

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Inactive Ingredients

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Dimethyl Sulfone, Magnesium Chloride, Cetyl Alcohol, Glyceryl Stearate, Polyglyceryl-6 Palmirate/Succinate, Glycerin, ▶

Drug Facts (continued)

Hydroxyacetophenone, Tocopheryl Acetate, Xanthan Gum, Caprylyl Glycol, 1,2-Hexanediol, Acacia Senegal Gum, Perlaerythryl Tetra-Di-T-Butyl Hydroxyhydrocinnamate, Magnesium Sulfate, Potassium Chloride, Sodium Chloride, Calcium Chloride

Questions or Comments?

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Listed with the FDA
Distributed by Asutra
4158 W. Montrose Ave.
Chicago, IL 60641
Manufactured by Wanadis Kft
Budapest, Hungary

RECOVERY ROLL-ON

menthol, camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75249-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	5 g in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ACACIA (UNII: 5C5403N26O)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75249-008-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/17/2022	

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(75249-008)

Revised: 2/2023

SOLITEINT KOZMETIKUM GYARTO ES FORGALMAZO TERMELO ES KERESKEDELMI KORLATOLT FELELOSSEGU TARSASAG