

REAL TIME PAIN RELIEF THERAPEUTIC HAND CREAM- trolamine salicylate 10% lotion
Cosmetic Specialty Labs, Inc.

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.

Real Time Pain Relief Therapeutic Hand Cream

Active ingredient

Trolamine Salicylate - 10%

Purpose

Topical Analgesic

Purpose

Topical Analgesic

Uses

Uses: □temporarily relieves minor pain associated with • arthritis • simple backache • muscle strains • bruises • cramps

Warnings

For external use only

Allergy alert: if prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

□**When using this product** • use only as directed • avoid contact with eyes or mucous membranes • do not apply to wounds or damaged skin

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of the children. If product is swallowed, get medical help or contact a Poison Control Center right away

Directions

adults and children over 2 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but no more than 4 times daily

children 2 years or younger: ask a doctor

Inactive ingredients:

Aloe Barbadosensis Leaf, Arnica Montana Flower Extract, Butylene Glycol, Butyrospermum Parkii (Shea Butter), C13-14 Isoparaffin, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Emu Oil, Fragrance, Laureth-7, Methylsulfonylmethane, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyacrylamide, Purified Water, Salix Alba (Willow) Bark Extract, Tocopheryl Acetate, Triethanolamine.

Package Label and Principal Display Panel



THERAPEUTIC
HAND CREAM

Provides Temporary Relief from:
Arthritis, Muscle Strains, Sprains,
Bruises, Cramps.



Topical Analgesic Lotion

Net Wt. 12 Fl. Oz. / 345 mL

Drug Facts

Active Ingredient	Purpose
Trolamine Salicylate 10.0%	Topical analgesic
Uses temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps	
Warnings for external use only	
Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.	
When using this product ■ use only as directed ■ avoid contact with eyes or mucous membranes ■ do not apply to wounds or damaged skin	
Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness is present ■ Irritation develops	
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions: adults and children over 2 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 4 times daily children 2 years or younger: ask a doctor	
Inactive Ingredients Aloe Barbadosensis Leaf, Arnica Montana Flower Extract, Butylene Glycol, Butyrospermum Parkii (Shea Butter), C13-14 Isoparaffin, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Emu Oil, Fragrance, Laureth-7, Methylsulfoniummethane, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyacrylamide, Purified Water, Salix Alba (Willow) Bark Extract, Tocophery Acetate, Triethanolamine.	

NDC #58133-400-12
Distributed by: RTPR LLC,
Edmond, OK 73003
www.RTPR.com



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REAL TIME PAIN RELIEF THERAPEUTIC HAND CREAM

trolamine salicylate 10% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 133-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TROLAMINE SALICYLATE (UNII: H8 O40 40 BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	TROLAMINE SALICYLATE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EMU OIL (UNII: 344821WD61)	
LAURETH-7 (UNII: Z95S6G8201)	
BUTYROSPERMOL (UNII: 6SF0L0FL42)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	
2-(2-(2-(2-PHENOXYETHOXY)ETHOXY)ETHOXY)ETHANOL (UNII: Y050HYR4XA)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
SALIX ALBA BARK (UNII: 205MXS71H7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-400-15	45 mL in 1 TUBE; Type 0: Not a Combination Product	12/16/2014	
2	NDC:58133-400-04	120 mL in 1 TUBE; Type 0: Not a Combination Product	12/16/2014	
3	NDC:58133-400-12	345 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/16/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/16/2014	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Registrant - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-400)

