CANNESSENTIA PAIN RELIEF CREAM- trolamine salicylate cream CannEssentia 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.

CannEssentia Pain Relief Cream

Active ingredient

Trolamine salicylate 10%

Purpose

Topical analgesic

Uses

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

- simple backache
- arthritis
- 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. Read and follow all directions and warnings on this label
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- avoid contact with eyes or mucous membranes
- do not apply to wounds or damaged, broken or irritated skin
- do not use at the same time as other topical analgesics

Stop use and ask a doctor if

- condition worsens
- symptoms last 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 12 years:

- apply generously to affected area
- massage into painful area until thoroughly absorbed into skin
- repeat as necessary, but not more than 3to 4 times daily

children 12 years and younger: ask a doctor

Inactive ingredients

coconut oil, cod liver oil (contains vitamin A & vitamin D), fragrances, hemp seed oil, lanolin, light mineral oil, medium-chain triglycerides, microcrystalline wax, paraffin, petrolatum, sodium chloride, terpene essential oil, yellow wax

Principal Display Panel

NDC # 72418-333-15

CannEssentia

Pain Relief Cream

(Trolamine Salicylate)

NET WT 0.5 OZ (14.17 g)



CANNESSENTIA PAIN RELIEF CREAM

trolamine salicylate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72418-333
Route of Administration	TOPICAL		
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 g

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
COCONUT OIL (UNII: Q9L0O73W7L)		
COD LIVER OIL (UNII: BBL281NWFG)		
CANNABIS SATIVA SEED OIL (UNII: 69 VJ1LPN1S)		
LANOLIN (UNII: 7EV65EAW6H)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)		
PARAFFIN (UNII: 1900E3H2ZE)		
PETROLATUM (UNII: 4T6H12BN9U)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72418-333- 15	1 in 1 CARTON	0 3/0 1/20 19	
1	14.17 g in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 3/0 1/20 19	

Labeler - CannEssentia LLC (031775148)

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