# PAIN RELIEVING TOPICAL ANALGESIC- trolamine salicylate 10% cream Top Care

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.

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### **Drug Facts**

Active ingredient	Purpose	
Trolamine Salicylate - 10%	Topical Analgesic	

### 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 no more than 4 times daily Children 12 years or younger: ask a doctor.

**Uses** Itemporarily reliefs 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 taking a bath or shower within 1 hour before or after applying • do not bandage tightly or use with a heating pad • avoid contact with eyes or muscous 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

## **Inactive ingredients**

Aloe Barbadensis Leaf Juice, Cetyl Alcohol, Glycerin, Methylparaben, Mineral Oil, Potassium Phosphate, Propylparaben, Stearic Acid, Triethanolamine, Water



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...Topical Analgesic

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\*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Aspercreme®.

## PAIN RELIEVING TOPICAL ANALGESIC

trolamine salicylate 10% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-884
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
		10 1 100

TROLAMINE SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ) TROLAMINE SALICYLATE 10 g in 100 g

#### **Inactive Ingredients**

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glycerin (UNII: PDC6A3C0OX)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
Propylparaben (UNII: Z8IX2SC1OH)	
Stearic Acid (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
Water (UNII: 059QF0KO0R)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:36800-884-03	1 in 1 CARTON 08/18/2014			
1	1 89 g in 1 TUBE; Type 0: Not a Combination Product			
Marketing Information				
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not find	al part348	08/18/2014		

## Labeler - Top Care (006935977)

## Registrant - Product Quest Mfg (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-884) , label(36800-884)

Revised: 6/2018

Top Care