ARTHRITIS LEADER- trolamine salicylate cream Cardinal Health

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.

Drug Facts

Trolamine Salicylate 10.0%

Uses

Temporarily relieves minor pain associated with: arthritis, simple backache, muscle strains, sprains, bruises, and cramps.

Warnings

For external use only.

Allergy alert: if prone to allergic reaction from aspirin or salicylate, contact a doctor before use

When using this product: use only as directed, do not bandage tightly or use with a heating pad, avoid contact with eyes or mucous membranes, and do no apply to wounds or damaged skin

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

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

Directions

Adults and children over 12 years of age: apply generously to affected area, massage into painful area until thoroughly absorbed into skin, repeat as necessary, but not more than 4 times daily. Children 12 years or younger: ask a doctor.

Inactive ingredients

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

Purpose

Pain relieving gel.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

Leader Arthritis Cream with Aloe.



ARTHRITIS LEADER trolamine salicylate cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37205-750

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

cuve ingredient/Active wrotety					
Ingredient Name	Basis of Strength	Strength			
Trolamine Salicylate (UNII: H8O4040BHD) (Trolamine - UNII:9O3K93S3TK)	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: A2I8 C7HI9 T)				
Mineral Oil (UNII: T5L8T28FGP)				
PO TASSIUM PHO SPHATE, DIBASIC (UNII: CI71S98N1Z)				
Propylparaben (UNII: Z8IX2SC1OH)				
Stearic Acid (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 9O3K93S3TK)				
Water (UNII: 059QF0KO0R)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:37205-750-21	1 in 1 CARTON					
1		85 g in 1 TUBE					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	11/0 1/20 12				

Labeler - Cardinal Health (097537435)

Revised: 10/2012 Cardinal Health