PAIN RELIEF CREAM- trolamine salicylate cream ALLURE 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.

DRUG FACTS

Active Ingredients:

Trolamine Salicylate - 10%

Purpose:

Topical Analgesic

Uses: For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains and bruises.

For external use only.

Ask a doctor before use if you have a propensity for allergic reactions to aspirin or salicylate.

When using this product: Avoid contact with eyes or mucous membranes; if contacts occurs, flush with water for 15 minutes. Do not apply to wounds or damaged skin.

If pain persist more than 7 days or redness or irritation is present or in condition affecting children under 12 years of age, consult a physician immediately.

Keep out of reach of children.

Inactive ingredients

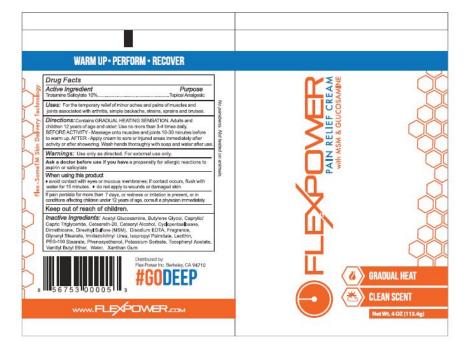
Acetyl Glucosamine, Butylene Glycol, Capriylic/ Capric Triglyceride, Ceteareth-20, Cetearyl Alcohol, Cyclopentasilaxane, Dimethicone, Dimethyl Sulfone (MSM), Disodium EDTA, Fragrance, Glyceryl Stearate, Imidazolidinyl Uraea, Isopropyl Palmitate, Lecithine, PEG-100 Stearate, Phenoxy ethanol, Potassium Sorbitate, Tocopheryl Acetate, Vanillyl Butyl Ethar, Water, Xanthan Gum.

Contains Gradual Heating Sensation. Adults and Children 12 years of age and older: use no more than 3-4 times daily. Before Activity-Massage onto muscles and joints 10-30 minutes before to warm up. After - Apply cream to sore or injured areas immediately after activity or after showering. Wash hands thoroughly with soap and water after use

Distributed by:

Flex Power Inc.

Berkeley, CA 94710



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WARM UP • PERFORM • RECOVER

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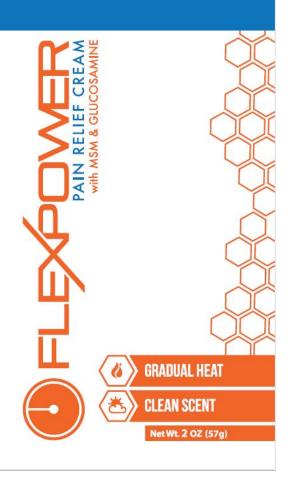
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PAIN RELIEF CREAM

trolamine salicylate cream

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Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength		
TROLAMINE SALICYLATE (UNII: H8 O 40 40 BHD) (SALICYLIC ACID - UNII: O 414PZ4LPZ)	TROLAMINE SALICYLATE	100 mg in 1 g		

Inactive Ingredients

inactive ingredients	
Ingredient Name	Strength
DISODIUM ACETYL GLUCO SAMINE PHO SPHATE (UNII: SC89 MF712W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CETEARETH-2 (UNII: ATB309OMWW)	
DIMETHICO NE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILO XANE) (UNII: UF7620L1W6)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
N-(1,3-BIS(HYDROXYMETHYL)-2,5-DIOXO-4-IMIDAZOLIDINYL)-N,N'-BIS(HYDROXYMETHYL)UREA(UNII:N9VX1IBW6K)	
ISOPROPYL PALMITATE (UNII: 8 CRQ2TH6 3M)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9 H2L21V7U)	

Packaging

I	# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1 NDC:62742-	1091-1 57 g in 1 TUBE; Type 0: No	ot a Combination Product	11/27/2017	

Marketing Information

8			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/27/2017	

Labeler - ALLURE LABS INC. (926831603)

Registrant - Allure Labs Inc. (926831603)

Establishment					
Name	Address	ID/FEI	Business Operations		
ALLURE LABS INC.		926831603	manufacture(62742-4091)		

Revised: 11/2017 ALLURE LABS INC.