LUCKY SUPERSOFT MEDICATED BODY TRIPLE ACTION- menthol zinc oxide powder Delta Brands 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.

Lucky Crnstrch menthol zinc oxide Powder

Active Ingredient

Menthol 0.15% Zinc oxide 1.0%

Purpose

Anti-itch

Skin protectant

Uses

temporarily relieves the pain and itch associated with:

■ minor cuts ■ sunburn ■ insect bites ■ scrapes ■ minor burns ■ minor skin irritations

Warnings

For external use only

Do not use on

■ broken skin ■ deep or puncture wounds ■ serious burns

When using this product

■ avoid contct with eyes ■ keep away from face and mouth to avoid breathing powder

Stop use and ask a doctor if

■ if condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ redness, irritation, swelling or pain persists or increases

Keep out of reach of children.

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

Directions

■ for aduts and children 2 years and older: apply freely up to 3 or 4 times daily ■ for children under 2 years: ask a doctor ■ for best results dry skin thoroughly before applying

Other information

■ this product is sold by weight, not by volume ■ settling will occur during handling & shipping

Inactive ingredients

acacia seyal gum, eucalyptol, methyl salicylate, salicylic acid, sodium bicarbonate, thymol, tricalcium phsphate, zea mays (corn) starch, zinc stearate

Package Label





menthol zinc oxide powder

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:20276-980

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 1 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
SALICYLIC ACID (UNII: O414PZ4LPZ)				
THYMOL (UNII: 3J50XA376E)				
ZINC STEARATE (UNII: H92E6QA4FV)				
GUM TALHA (UNII: H18F76G097)				
EUCALYPTOL (UNII: RV6J6604TK)				
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:20276- 980-08	227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2017			
2	NDC:20276- 980-14	397 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2022			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	12/11/2017			

Labeler - Delta Brands Inc (102672008)

Revised: 5/2022 Delta Brands Inc