AMERFRESH MEDICATED- menthol and zinc oxide powder Amercare Products 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.

AMERFRESH® MEDICATED BODY POWDER

Drug Facts

Active Ingredients	Purpose
Menthol 0.15%	Anti-itch
Zinc Oxide 1.0%	Skin Protection

Uses

temporarily relieves the pain and itch associated with:

- Minor cuts
- Sunburn
- Insect Bites
- Scrapes
- Prickly Heat
- Minor Burns
- Rashes
- Minor Skin Irritations
- Dries the oozing of poison ivy, oak and sumac.

Warnings

For external use only

Avoid contact with eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms do not get better within 7 days

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control right away.

Directions

adults and children 2 years and older	apply freely up to 3 or 4 times daily		
Children under 2 years	ask a doctor		
For best results dry skin thoroughly before applying			

Inactive Ingredients

Talc, Eucalyptol, Methyl salicylate, Salicylic acid, Thymol, Zinc stearate.

DISTRIBUTED BY AMERCARE PRODUCTS, INC

PRINCIPAL DISPLAY PANEL - 283g Container Label

AMERFRESH®

BONDED

FOR

PURITY

MEDICATED

BODY

POWDER

NET WT.10 OZ. (283g)





AMERFRESH MEDICATED

menthol and zinc oxide powder

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51460-0504

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Route	Λŧ	Δ	mini	CTPO	tion

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	0.15 g in 100 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	1 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
Talc (UNII: 7SEV7J4R1U)	97.4 g in 100 g		
Salicylic Acid (UNII: O414PZ4LPZ)			
Methyl Salicylate (UNII: LAV5U5022Y)			
Eucalyptol (UNII: RV6J6604TK)			
Thymol (UNII: 3J50XA376E)			
Zinc Stearate (UNII: H92E6QA4FV)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51460-0504-1	283 g in 1 CONTAINER		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	0 1/0 1/20 0 5		

Labeler - Amercare Products Inc (879289254)

Revised: 5/2011 Amercare Products Inc