

MEDICATED BODY POWDER- menthol and zinc oxide powder
MAGVERZ 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.

Medicated Powder

Actives

Menthol 0.15%
Zinc Oxide 1.0%

Inactives

Talc
Salicylic Acid
Methyl Salicylate
Eucalyptol
Thymol
Zinc Stearate
Acacia

Uses

Temporarily relieves the pain and itch associated with

Minor cuts

- Sunburn Insect Bites
- Scrapes Prickly
- HeatMinor
- Burns Rashes
- Minor Skin Irritations

Purpose

Temporarily relieves the pain and itch

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.

Warning

For external use only.

When using this product avoid contact with eyes.

Stop use and ask doctor if condition worsens, symptoms do not get better within 7 days.

Keep Out of Reach of Childrens

Keep out of reach of childrens.

Product Label

MEDICATED BODY POWDER			
menthol and zinc oxide powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59240-001
Route of Administration	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)	
Salicylic Acid (UNII: O414PZ4LPZ)	
ACACIA (UNII: 5C5403N26O)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59240-001-01	113 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/18/2013	

Labeler - MAGVERZ INC (078712269)

Registrant - MAGVERZ INC (078712269)