

**PERSONAL CARE - medicated body powder powder**  
**Personal Care 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.*

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**Personal Care Medicated Body Powder**

Active ingredients	Purpose
Menthol 0.15 percent	External analgesic
Zinc Oxide 1.0 percent	Skin protectant

Uses for the temporary relief of the pain and itch associated with:

- minor cuts - scrapes - sunburn - insect bites - prickly heat - rashes
- minor burns - minor skin irritation - dries the oozing of poison ivy, oak and sumac.

**Warnings**

For external use only

When using this product avoid contact with eyes.

Stop using and ask a doctor if

- condition worsens
- symptoms do not get better within 7 days or clear up and occur again within a few days

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

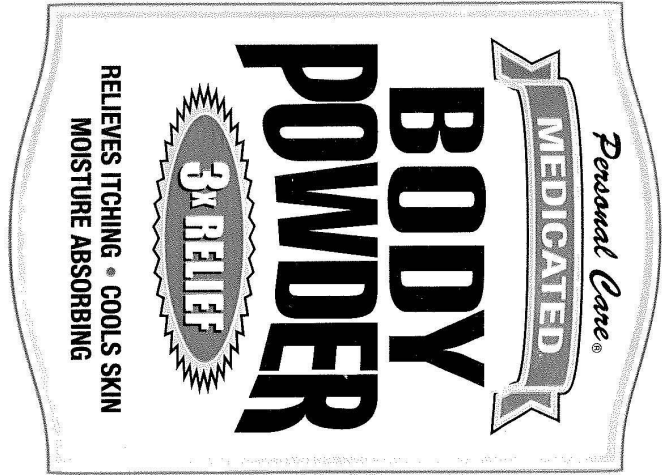
**Directions**

adults and children 2 years and older, apply freely up to 3 or 4 times daily

- under 2 years: ask a doctor before using
- for best results, dry skin thoroughly before use.

**Inactive ingredients**

talco, acacia, eucalyptus oil, methyl salicylate, salicylic acid, thymol, zinc stearate



# BODY POWDER

## Key Facts

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## PERSONAL CARE

medicated body powder powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	3 mg in 2 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Cation - UNII:13S1S8SF37)	Zinc Oxide	20 mg in 2 g

Inactive Ingredients	
Ingredient Name	Strength
Talc (UNII: 7SEV7J4R1U)	
Acacia (UNII: 5C5403N26O)	
Eucalyptol (UNII: RV6J6604TK)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Salicylic Acid (UNII: O414PZ4LPZ)	
Thymol (UNII: 3J50XA376E)	
Zinc Stearate (UNII: H92E6QA4FV)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9090-1	283 g in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2009	

**Labeler** - Personal Care Products, Inc. (603124298)**Establishment**

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture

Revised: 9/2009

Personal Care Products, Inc.