

PERSONAL CARE - medicated foot 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.

Personal Care Medicated Foot Powder

Active ingredients	Purpose
Menthol 1 percent	External analgesic

Uses for the temporary relief of the pain and itch associated with minor skin

irritation on the foot - absorbs excess moisture - helps control foot odor and

odor-causing bacteria - cools and soothes irritated skin

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

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

Directions

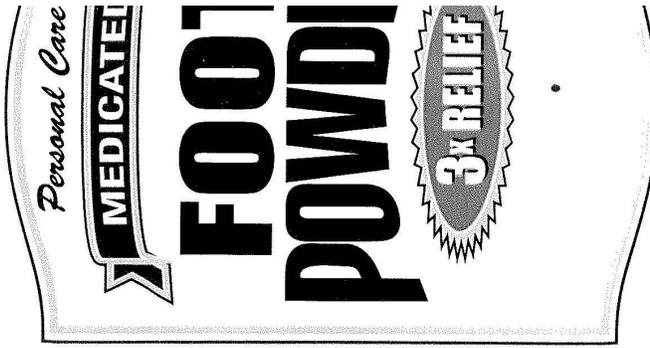
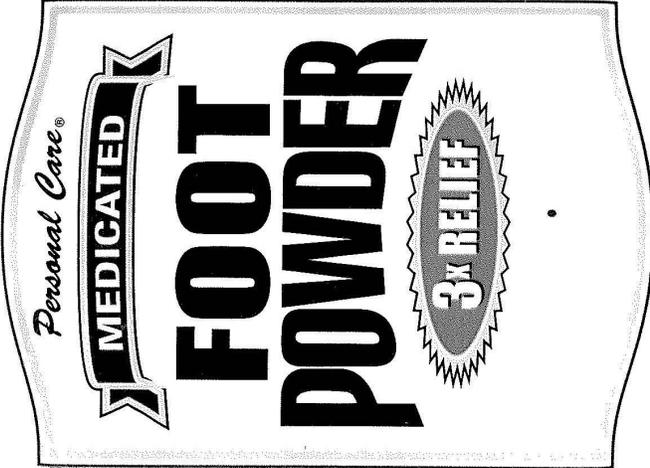
- adults and children 2 years and older, apply freely up to 3 or 4 times daily

- under 2 years: ask a doctor before using

- wash and dry feet, sprinkle powder liberally over feet, between toes, on bottoms of feet, and in shoes

Inactive ingredients

talco, sodium bicarbonate, acacia, benzethonium chloride, eucalyptus oil, peppermint oil



FOOT POWDER

Drugs Facts

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PERSONAL CARE

medicated foot powder powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9091
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	20 mg in 2 g

Inactive Ingredients

Ingredient Name	Strength
Talc (UNII: 7SEV7J4R1U)	
Sodium Bicarbonate (UNII: 8MDF5V39QO)	
Acacia (UNII: 5C5403N26O)	
Benzethonium chloride (UNII: PH41D05744)	
Eucalyptus Oil (UNII: 2R04ONIG62)	
Peppermint Oil (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9091-1	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.