MEDICATED BODY- menthol and zinc oxide powder
Universal Distribution Center LLC

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 Body Powder

Active Ingredients

Menthol 0.15%

Zinc Oxide 1.0%

Purpose

Anti-itch

Uses

For the temporary relief from pain and itching associated with minor cuts and burns, sunburn, scrapes, insect bites, and other minor skin irritation. Also for drying up poison oak, which helps control the growth of fungi associated with athlete's foot and jock itch.

Warning

For external use only.

Avoid contact with eyes.

If symptoms persist more than 7 days, worsen with use or return within a few days of cleaning up, discontinue use of this product and consult a doctor.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

Use after shower, bath or exercise. Use in footwear and on feet. Dry skin completely before applying. For adults and children over 2 years; apply to affected area not more than 3 or 4 times daily. Children Under 2 Years; Consult a doctor.

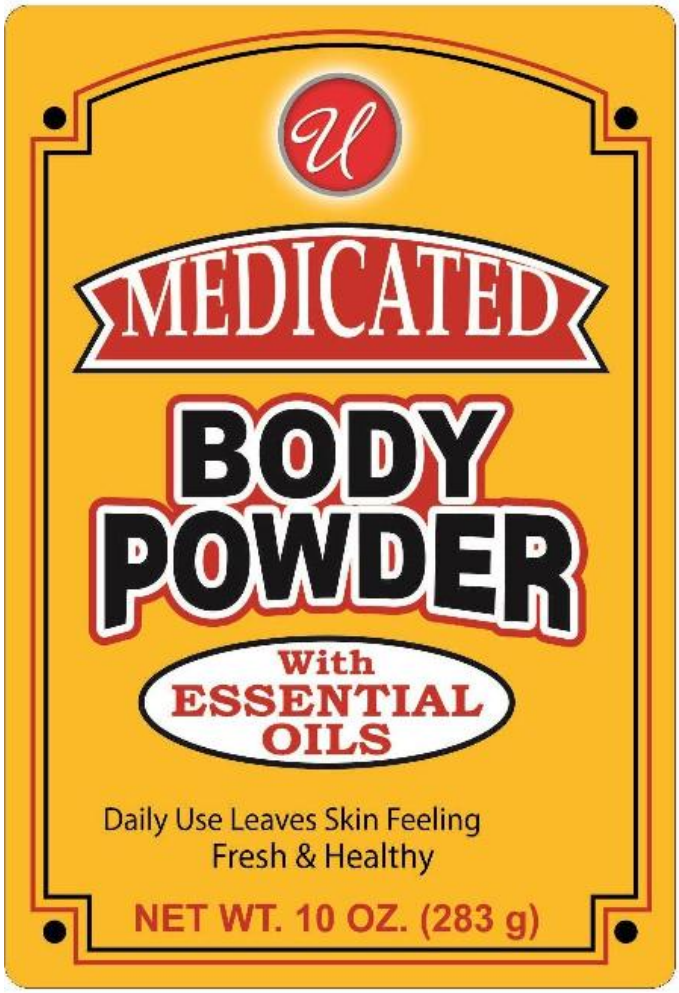
Inactive Ingredients

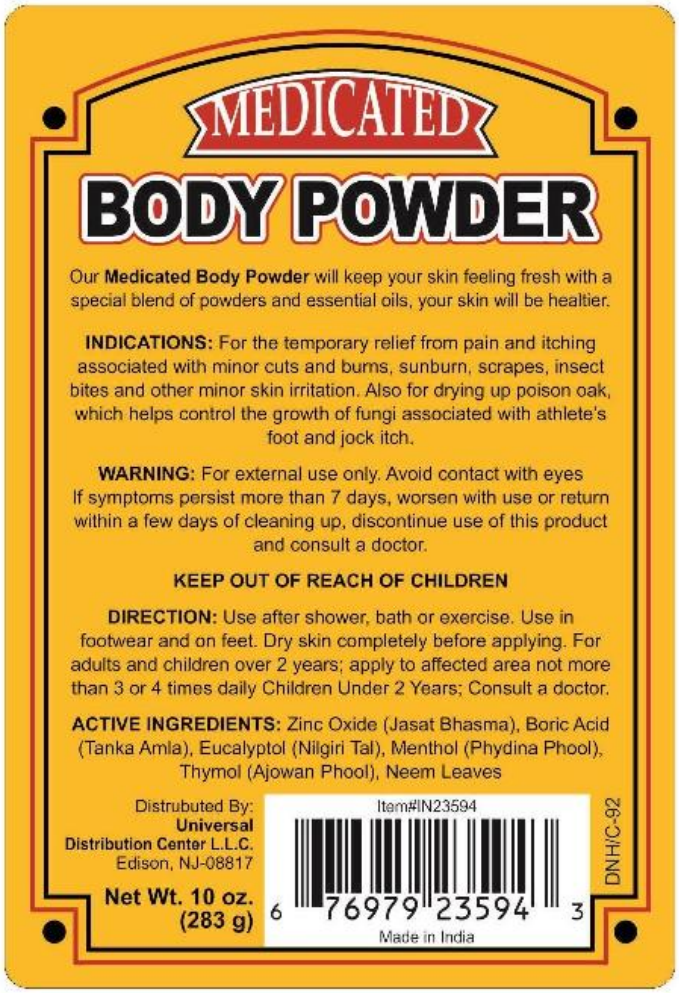
talc, acacia, eucalyptus oil, methyl salicylate, salicylic acid, thymol, zinc stearate.

PRINCIPAL DISPLAY PANEL

MEDICATED BODY POWDER

NET WT. 10 OZ. (283g)





MEDICATED BODY

menthol and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52000-024
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)	
ACACIA (UNII: 5C5403N26O)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
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:52000-024-25	283 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/03/2015	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52000-024)

Revised: 11/2015 Universal Distribution Center LLC