

MEDICATED BODY POWDER- menthol powder
Rejoice International 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 Body Powder

Active Ingredients	Purpose
Menthol 1.0%	Anti-itch

Uses

temporarily relieves the pain and itch associated with minor skin irritation on the foot

- provides itch relief
- absorbs excess moisture
- helps control foot odor and odor-causing bacteria
- cools and soothes irritated skin

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

XtraCare

Medicated Foot Powder

3x Action

Itch Relieving

Odor Controlling

Moisture Absorbing

Directions

adults and children 2 years and older

apply freely up to 3 or 4 times daily

children under 2 years

ask a doctor before using

Thoroughly wash and dry feet, sprinkle powder liberally over feet, between toes, and on bottom of feet. For best results apply to affected areas up to 3 or 4 times daily. Sprinkle inside shoes for maximum freshness.

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Warnings

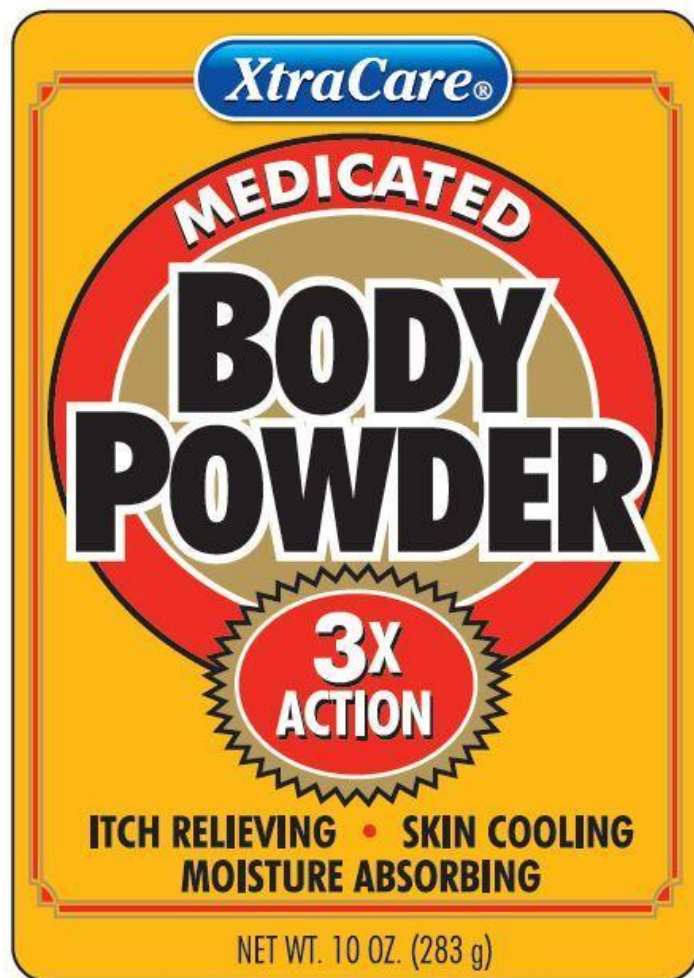
For external use only

- avoid contact with eyes

Stop using and ask a doctor if

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

□ **Inactive ingredients** talc, sodium bicarbonate, acacia, benzethonium chloride, eucalyptus oil, peppermint oil



BODY POWDER

Drugs Facts	
Active ingredients	Purpose
Menthol 0.15%.....	Anti-itch
Zinc Oxide 1.0%.....	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 ■ 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
children under 2 years	ask a doctor before using
For best results, dry skin thoroughly before use.	
Inactive ingredients talc, acacia, eucalyptol, methyl salicylate, salicylic acid, thymol, zinc stearate.	
QUESTIONS/COMMENTS? 1-855-345-5575	
DISTRIBUTED BY REJOICE INTERNATIONAL, INC NORTHVILLE, MI 48168 U.S.A. MADE IN INDIA	



MEDICATED BODY POWDER			
menthol powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-079
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 CATION - UNII:13S1S8SF37)		ZINC CATION	1 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
TALC (UNII: 7SEV7J4R1U)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
ACACIA (UNII: 5C5403N26O)			

SALICYLIC ACID (UNII: O414PZ4LPZ)	
EUCALYPTOL (UNII: RV6J6604TK)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-079-01	283 g in 1 PACKAGE; Type 0: Not a Combination Product	06/15/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/15/2015	

Labeler - Rejoice International Inc. (078741245)

Registrant - Jell Pharmaceuticals Pvt Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(57337-079)

Revised: 11/2022

Rejoice International Inc.