

MEDICATED BODY POWDER- menthol powder

New Pride Corp

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.

Pride Medicated Body Powder

Drug Facts

Active Ingredients

Menthol 0.15 %

Purpose

External Analgesic

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 irritations
- dries the oozing of poison ivy, oak and sumac.

Warnings

For external use only

When use this product

Avoid contact with eyes. Not for genital area.

Stop use and ask a doctor if

- condition worsens
- Redness, irritation, swelling or pain persist or increases
- symptoms do not get better within 7 days or clear up and occur again within a few days

Keep out of reach of children

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- adults and children 2 years of age and over, apply freely up to 3 or 4 times daily
- Children under 2 years: consult a physician
- for best results, dry skin thoroughly before use

Inactive Ingredients

acacia seyl gum, eucalyptol, methyl salicylate, salicylic acid, sodium bicarbonate, thymol, tricalcium phosphate, zea mays (corn starch), zinc oxide, zinc stearate

Equate Medicated Body Powder Original

SIZE : 76 x 108mm



MEDICATED BODY POWDER

menthol powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58037-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 g in 283 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
ACACIA (UNII: 5C5403N26O)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
MENTHYL SALICYLATE, (+/-)- (UNII: 43XOA705ZD)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
ZEA MAYS WHOLE (UNII: 1G5HNE09V8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58037-001-01	283 g in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2020	

Labeler - New Pride Corp (884264198)

Registrant - Jell Pharmaceuticals pvt ltd (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(58037-001)

