

**MEDICATED BODY POWDER- menthol powder**  
**Jell Pharmaceuticals Pvt Ltd**

*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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**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 using 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

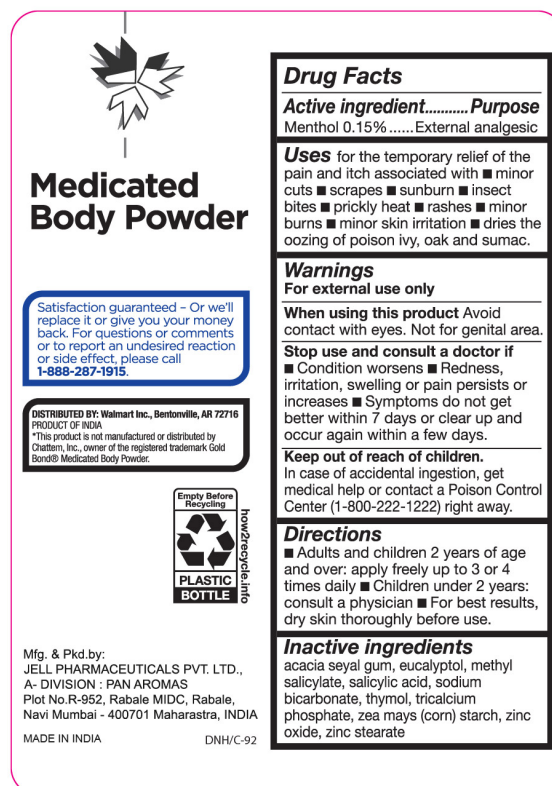
- adults and children 2 years of age and over, apply freely up to 3 or 4 times daily
- Children under 2 years: consult a physician
- for best results, dry skin thoroughly before use

## 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



### Drug Facts

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Menthol 0.15% .....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 irritation ■ dries the oozing of poison ivy, oak and sumac.

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menthol powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30400-506
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:30400-506-01	283 g in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2020	

## Marketing Information

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

**Labeler** - Jell Pharmaceuticals Pvt Ltd (726025211)

**Registrant** - Jell Pharmaceuticals pvt ltd (726025211)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(30400-506)

