

HEALTH SMART MEDICATED BODY- menthol and zinc oxide powder
International Wholesale Inc dba Home Smart Products

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.

Health Smart Medicated Body Powder (Talc Free)

Active Ingredients

Menthol 0.15%

Zinc Oxide 1.0%

Purpose

External Analgesic

Skin Protectant

Uses

For the temporary relief of pains 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.

When using this product avoid contact with eyes.

Consult a doctor and discontinue use if

- condition worsens
- symptoms do not get better within 1 week or clear up and occurs again within a few days.

Keep out of reach of children

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

Directions

adults and children 2 years and over

- apply to the affected area not more than 3 or 4 times daily.
- children under 2 years of age: consult a physician.

- for best results, dry skin thoroughly before use.

Inactive Ingredients

acacia seyal gum, eucalyptus oil, methyl salicylate, salicylic acid, sodium bicarbonate, thymol, tricalcium phosphate, zea mays (corn starch) zinc stearate.

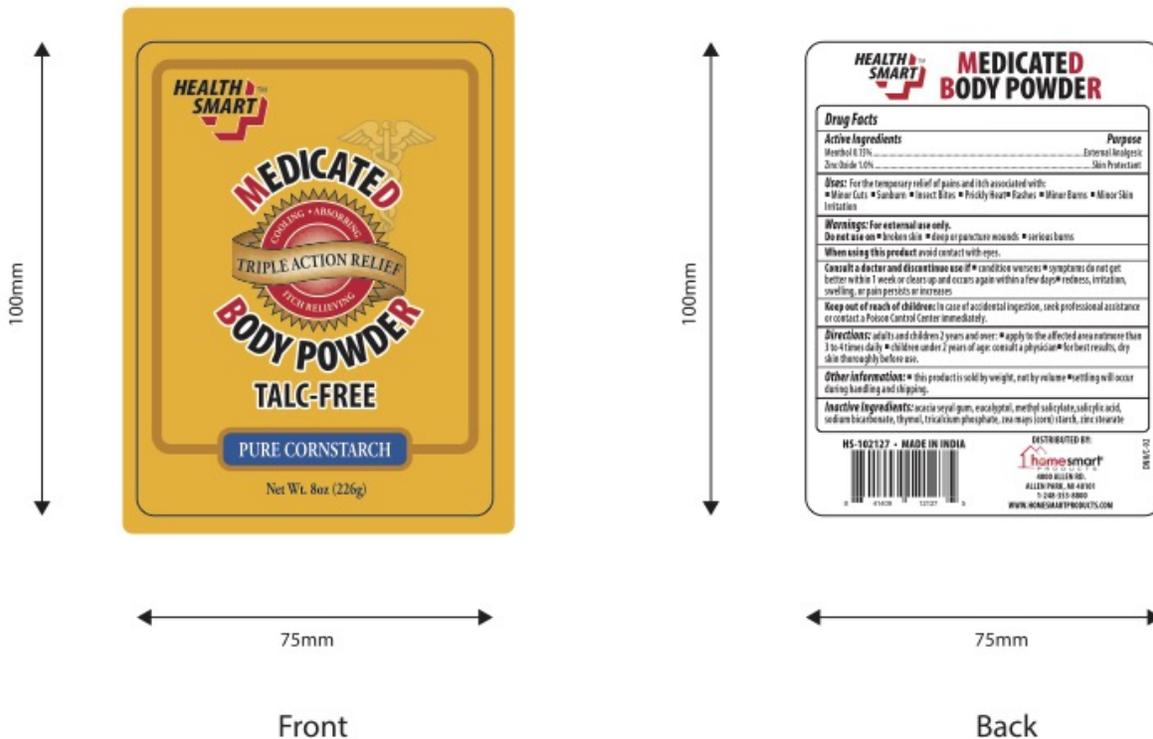
PRINCIPAL DISPLAY PANEL

HEALTH SMART MEDICATED BODY POWDER

NET WT. 10 OZ. (283g)

NAME - 8oz Medicated Body Powder

DATE - 22-02-2023



HEALTH SMART MEDICATED BODY

menthol and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-030
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
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ACACIA (UNII: 5C5403N26O)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	
ZEA MAYS SUBSP. MAYS WHOLE (UNII: 1G5HNE09V8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-030-01	283 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/27/2014	

Labeler - International Wholesale Inc dba Home Smart Products (161872676)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-030)

Revised: 9/2023

International Wholesale Inc dba Home Smart Products