ASTONEA MEDICATED BODY POWDER POWDER- menthol, zinc oxide powder
ASTONEA LABS PRIVATE LIMITED

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.

Astonea Medicated Body Powder

Drug Facts

Active Ingredients

Menthol 0.15 %

Zinc Oxide 1.0%

Purpose

Anti-itch

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

Keep out of reach of children

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

Warnings

For external use only

When usin this product

- Avoid contact with eyes.
- Keep away from face and mouth to avoid inhalation
- Not for genital area.

Stop use and ask a doctor if

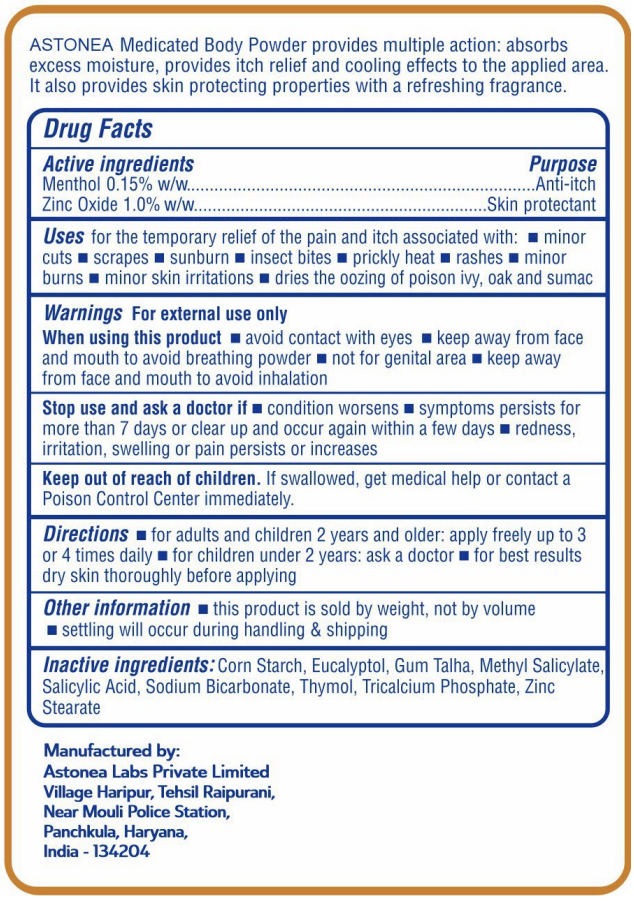
- condition worsens
- symptoms do not get better within 7 days or clear up and occur again within a few days

Directions

- adults and children 2 years and older, apply freely up to 3 or 4 times daily
- under 2 years: ask a doctor before using
- for best results, dry skin thoroughly before use

Inactive Ingredients

Corn Starch, Eucalyptol, Gum Talha, Methyl Salicylate, Salicylic Acid, Sodium Bicarbonate, Thymol, Tricalcium Phosphate, Zinc Stearate



ASTONEA MEDICATED BODY POWDER POWDER

menthol, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77338-403
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
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STARCH, CORN (UNII: O8232NY3SJ)	
GUM TALHA (UNII: H18F76G097)	
EUCALYPTOL (UNII: RV6J6604TK)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
THYMOL (UNII: 3J50XA376E)	
ZINC STEARATE (UNII: H92E6QA4FV)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-403-10	283 g in 1 BOTTLE; Type 0: Not a Combination Product	10/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/05/2021	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

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