

**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 accidental ingestion, get medical help or contact a Poison Control Center right away.

Warnings

For external use only

When use in 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 provides multiple action: absorbs excess moisture, provides itch relief and cooling effects to the applied area. It also provides skin protecting properties with a refreshing fragrance.

Drug Facts	
Active ingredients	Purpose
Menthol 0.15% w/w.....	Anti-itch
Zinc Oxide 1.0% w/w.....	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	
Warnings For external use only	
When using this product ■ avoid contact with eyes ■ keep away from face and mouth to avoid breathing powder ■ not for genital area ■ keep away from face and mouth to avoid inhalation	
Stop use and ask a doctor if ■ condition worsens ■ symptoms persists for more than 7 days or clear up and occur again within a few days ■ redness, irritation, swelling or pain persists or increases	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions ■ for adults and children 2 years and older: apply freely up to 3 or 4 times daily ■ for children under 2 years: ask a doctor ■ for best results dry skin thoroughly before applying	
Other information ■ this product is sold by weight, not by volume ■ settling will occur during handling & shipping	
Inactive ingredients: Corn Starch, Eucalyptol, Gum Talha, Methyl Salicylate, Salicylic Acid, Sodium Bicarbonate, Thymol, Tricalcium Phosphate, Zinc Stearate	

Manufactured by:
 Astonea Labs Private Limited
 Village Haripur, Tehsil Raipurani,
 Near Mouli Police Station,
 Panchkula, Haryana,
 India - 134204

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)