

**MENTHOL AND ZINC OXIDE- menthol and zinc oxide ointment  
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.*

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**ASTONEA Tender Calm**

**Menthol 0.44% w/w.....External Analgesic**

**Zinc Oxide 20.625% w/w..... Skin Protectant**

***Active Ingredients***

**Menthol 0.44% w/w**

**Zinc Oxide 20.625% w/w**

***Purpose***

Menthol 0.44% w/w.....External Analgesic

Zinc Oxide 20.625% w/w..... Skin Protectant

***uses***

A moisture barrier that prevents and helps heal skin irritations from;

- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage (peri-wound skin)
- minor burns
- cuts
- scrapes
- itching

**Warnings:**

**■For external use only ■Not for deep or puncture wounds ■Avoid contact with eyes**

***Stop use and ask a doctor if***

- Condition worsens
- Symptoms last more than 7 days or clear up and occur again within a few days

**Keep Out Of Reach Of Children****Keep Out Of Reach Of Children**

If swallowed , get medical help or contact a Poison Control Center right away.

**Dosage & Administration:**

- Clean skin with mild skin cleanser
- Pat dry or allow to air dry
- Apply a thin layer of Calasoothe to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection

**Inactive Ingredients**

Calamine, Glycerine, Lanolin, Light Liquid Paraffin, Petrolatum, Thymol, Tocopheryl Acetate

**Principal Display Panel**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Menthol 0.44% w/w .....	External Analgesic
Zinc Oxide 20.625% w/w .....	Skin Protectant
<b>Uses</b> ■ A moisture barrier that prevents & helps heal skin irritation from: ■ Urine ■ Diarrhea ■ Perspiration ■ Fistula drainage ■ Feeding tube site leakage ■ Wound drainage (peri-wound skin) ■ Minor burn ■ Cuts ■ Scrapes ■ Itching	
<b>Warnings</b> ■ For external use only ■ Not for deep or puncture wounds ■ Avoid contact with eyes	
<b>Stop use and ask a doctor if</b> ■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again within a few days	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Cleanse skin with mild skin cleanser ■ Pat dry or allow to air dry ■ Apply a thin layer of Skin Protectant to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection	
<b>Other Information</b> ■ Store at room temperature 20°-25°C (68°-77°F)	
<b>Inactive Ingredients</b> Calamine, Glycerine, Lanolin, Light Liquid Paraffin, Petrolatum, Thymol, Tocopheryl Acetate	

Patient Name:  
Room #:

# ASTONEA

## Skin Protectant

with Cooling Menthol  
and Zinc Oxide



SOOTHES AND  
PROMOTES HEALING

4 Oz. (113g)

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

HR/COSMETICS 308-COS(H)

### MENTHOL AND ZINC OXIDE

menthol and zinc oxide ointment

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77338-013
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.625 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>THYMOL</b> (UNII: 3J50XA376E)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-013-23	113 g in 1 TUBE; Type 0: Not a Combination Product	08/17/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/17/2022	

**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022

ASTONEA LABS PRIVATE LIMITED