

**MENTHOL AND ZINC OXIDE- menthol and zinc oxide ointment
ASTONEA LABS PRIVATE LIMITED**

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

Drug Facts	
Active Ingredients	Purpose
Menthol 0.44% w/w	External Analgesic
Zinc Oxide 20.625% w/w	Skin Protectant
Uses ■ 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	
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. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ 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	
Other Information ■ Store at room temperature 20°-25°C (68°-77°F)	
Inactive Ingredients 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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

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 Drug	M016	08/17/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)