

S-OINT PRODERM SKIN PROTECTANT- menthol, zinc oxide ointment
GLOBAL PHARMA HEALTHCARE 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.

S-Oint PRODERM: SKIN PROTECTANT OINTMENT

Drug Facts

ACTIVE INGREDIENT

Menthol 0.44% w/w

Zinc Oxide 20.625% w/w

PURPOSE

External Analgesic

Skin Protectant

INACTIVE INGREDIENTS

Calamine, Glycerine, Phenol, Lanolin, Heavy Liquid Paraffin, Sodium Bicarbonate, Thymol, White Soft Paraffin

INDICATIONS & USAGE

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

• Not for deep or puncture wounds. • Avoid contact with eyes. • If condition worsens or does not improve within 7 days, consult a doctor

Keep out of reach of children.

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

DIRECTIONS

Cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply a thin layer of Ointment 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 between:15-30°C (59-86°F)

Questions or comments?

1-800-572-6632 between 9am and 4 pm EST, Monday-Friday.

PROTECTS, SOOTHES AND PROMOTES HEALING

✓ Moisture barrier ✓ Rash relief ✓ Soothes skin irritation

Manufactured by :

Global Pharma Healthcare Pvt. Ltd.,


A-9, SIDCO Pharmaceutical Complex,

Alathur-603 110 - INDIA.

www.global-pharma.com

Packaging

NDC 73921-019-30	S-Oint	Net Wt. 30 gms
PRODERM: SKIN PROTECTANT OINTMENT		
PROTECTS, SOOTHES AND PROMOTES HEALING		
Menthol 0.44% v/v, Zinc Oxide 20.625% v/v ✓ Moisture barrier ✓ Rash relief ✓ Soothes skin irritation		
		 Global Pharma

Drug Facts ACTIVE INGREDIENT Menthol 0.44% w/w Zinc Oxide 20.625% w/w PURPOSE External Analgesic Skin Protectant INACTIVE INGREDIENTS Calamine, Glycerine, Phenol, Lanolin, Heavy Liquid Paraffin, Sodium Bicarbonate, Thymol, White Soft Paraffin INDICATIONS & USAGE A moisture barrier that prevents and helps heal skin irritations from; ■ Urine ■ Diarrhea ■ Perspiration ■ Fistula	Drug Facts <i>(continued)</i> OTHER INFORMATION Store between: 15-30°C (59-86°F) Questions or comments? 1-800-572-6632 between 9am and 4 pm EST, Monday- Friday.	Net Wt. 30 gms  Global Pharma	Mfg. Lic. No. : TN 00002175 Batch No. : Mfg. Date : Exp. Date :
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S-OINT PRODERM SKIN PROTECTANT

menthol, zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73921-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	4.4 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	206.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOL (UNII: 339NCG44TV)	
LANOLIN (UNII: 7EV65EAW6H)	

MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73921-019-30	1 in 1 CARTON	04/01/2021	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2021	

Labeler - GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED (860186917)

Establishment			
Name	Address	ID/FEI	Business Operations
GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED		860186917	manufacture(73921-019)

Revised: 3/2021

GLOBAL PHARMA HEALTHCARE PRIVATE LIMITED