PROSKI SOOTHE- menthol, zinc oxide cream
PHARMAMED USA INC

CALAMINE SKIN PROTECTANT CREAM

ACTIVE INGREDIENT

Menthol 0.44%

Zinc Oxide 20.625%

INDICATION

External Analgesic

Skin Protectant

USE

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

Do not use

• On deep or puncture wounds

When using this product

• 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 (1-800-222-1222) right away.

DIRECTIONS

• Cleanse skin with mild skin cleanser.

• Pat dry or allow to air dry.

• Apply a thin layer of PROSKI SOOTHE 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 15º-30º C (59º-86º F)

• Tamper evident. Do not use if packet is torn or cut. Do not use if seal is damaged.

INACTIVE INGREDIENTS

Ferric Oxide Red, Glycerin, Lanolin, Mineral Oil, Phenol, Sodium Bicarbonate, Thymol, White Petrolatum

QUESTIONS OR COMMENTS?

(754)-200-8994 (Mon-Fri 8 AM to 4 PM EST)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC: 84289-234-01

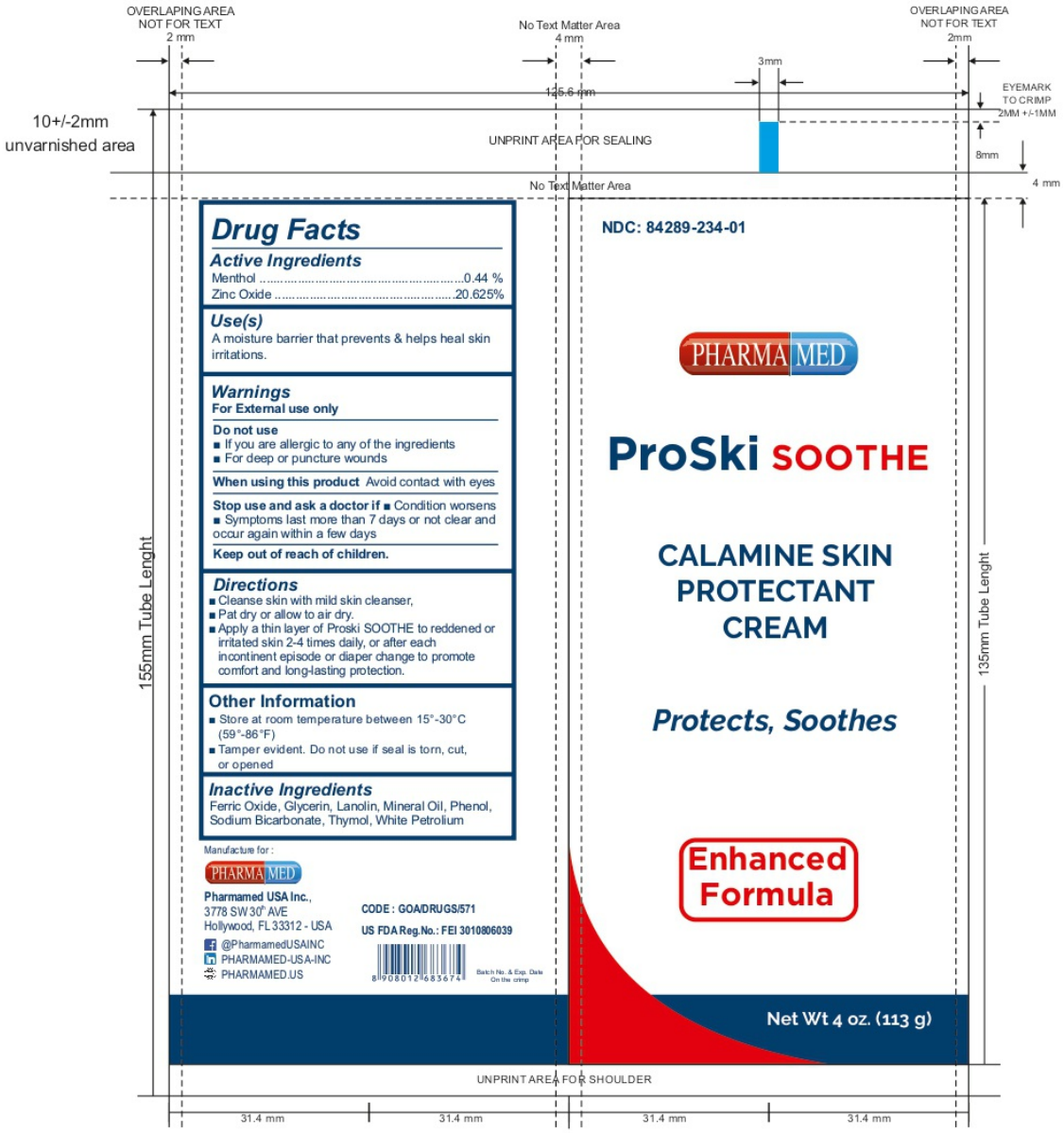
CALAMINE SKIN PROTECTANT CREAM

Protects, Soothes

Enhanced Formula

Net Wt 4 oz. (113 g)

GOA/DRUGS/571



PROSKI SOOTHE

menthol, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84289-234
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
PHENOL (UNII: 339NCG44TV)	
GLYCERIN (UNII: PDC6A3C0OX)	
THYMOL (UNII: 3J50XA376E)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN (UNII: 7EV65EAW6H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84289-234-01	113 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/01/2025	

Labeler - PHARMAMED USA INC (065607328)

Revised: 3/2025

PHARMAMED USA INC