

PROSHIELD PLUS SKIN PROTECTANT- dimethicone ointment
Smith & Nephew Medical Ltd

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.

PROSHIELD® PLUS Skin Protectant – dimethicone ointment

Drug Facts

Active ingredient

Dimethicone 1% w/w

Purpose

Skin Protectant

Uses

Helps prevent and temporarily protects chafed, chapped, or cracked skin.

Warnings

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

For external use only.

- When using this product do not get into eyes.

Stop use and ask physician 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

Apply liberally as needed.

Other information

Store at room temperature (15°C–25°C/59°F–77°F).

Inactive Ingredients

Calcium/Sodium PVM/MA Copolymer (Gantrez MS-955), Polyethylene Glycol 400 NF, Polyethylene

Glycol 3350 NF, Povidone USP.

Questions?

Please call 1-800-441-1261.

Smith & Nephew Medical Limited

101 Hessle Road, Hull HU3 2BN England

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Certain Marks Reg. U.S. Pat. and Tm. Off.

Made in USA

6566 18370

Internal Code 66801409

PRINCIPAL DISPLAY PANEL

REF 69740-044-09

NDC 69740-044-09

PROSHIELD[◇] PLUS

Skin Protectant

Dimethicone 1% w/w

PROSHIELD PLUS is a smooth, viscous, fragrance-free skin protectant, suitable for daily use. PROSHIELD PLUS adheres well to moist and dry skin and is easy to remove.

Net wt 4 oz (113 g)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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PROSHIELD PLUS SKIN PROTECTANT

dimethicone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-044
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	WHITE (OFF-WHITE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69740-044-09	113 g in 1 TUBE; Type 0: Not a Combination Product	01/01/1997	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/1997	

Labeler - Smith & Nephew Medical Ltd (216344051)