

SECURA DIMETHICONE PROTECTANT- dimethicone cream
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.

Secura Dimethicone Protectant

DRUG FACTS

ACTIVE INGREDIENTS

Dimethicone 5%

PURPOSE

Skin protectant

USES

- Helps treat and prevent diaper dermatitis
- Protects minor skin irritation associated with diaper dermatitis and helps protect from wetness
- Temporarily protects and helps relieve chapped or cracked skin and lips

WARNINGS

For external use only

When using this product

- do not get into 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

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

- Apply as needed
- Change wet and soiled diapers, garments, and linens promptly
- Cleanse the affected area and allow to dry
- Apply cream liberally as often as necessary with each diaper, garment or linen change; especially at bedtime or anytime when exposure to soiled diapers, garments, linens, feces, or urine may be prolonged

INACTIVE INGREDIENTS

water, petrolatum, isopropyl palmitate, propylene glycol, cetyl dimethicone copolyol, hexyl laurate, polyglycerol-4 isostearate, sodium chloride, paraffin, hydrogenated castor oil, beeswax, methylparaben, disodium EDTA, propylparaben

QUESTION OR COMMENTS?

1 800 876-1261

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL- TUBE (3.5 g)

Item #59435000

NDC 69740-322-01

Dimethicone Protectant

Skin Protectant

- Contains 5% Dimethicone
- For treatment and prevention of incontinence-associated dermatitis
- Helps prevent and temporarily protect, chafed, chapped, cracked or windburned skin or lips
- Non-irritating, fragrance-free
- Pediatric tested
- CHG Compatible
- Does not clog briefs

Smith & Nephew

Secura[®]

Dimethicone Protectant

Made in the USA for Smith & Nephew Medical Ltd, 101 Hessle Road, Hull, HU3 2BN, England

Certain marks reg'd in U.S. Pat and Tm Off.

Drug Facts

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Dimethicone 5%

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Certain marks reg'd in U.S. Pat. and Tm. Off. 79530

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REF 59435000

NDC 69740-322-01

Dimethicone Protectant

Skin Protectant

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smith&nephew

SECURA[®]

Dimethicone Protectant

Net wt. .12 oz (3.5 g)

EAN GS1

00369740322019

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL- TUBE (114 g)

Item #59432200

NDC 69740-322-00

Dimethicone Protectant

Skin Protectant

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- CHG Compatible
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Smith & Nephew

Secura[◇]

Dimethicone Protectant

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Drug Facts

Active ingredient

Dimethicone 5% Skin protectant

Purpose

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79494

EAN
00369740322002



Room #

Name

D

REF 59432200

NDC 69740-322-00

Dimethicone Protectant

Skin Protectant

- Contains 5% Dimethicone
- For treatment and prevention of incontinence-associated dermatitis
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SECURA[®]

Dimethicone Protectant

Net wt. 4 oz. (114 g)

SECURA DIMETHICONE PROTECTANT

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-322
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	1.7 mg in 1 g
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	45.1 mg in 1 g
METHYLPARABEN (UNII: A2I8C7HI9T)	2 mg in 1 g
PARAFFIN (UNII: I9O0E3H2ZE)	5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U)	90 mg in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	20 mg in 1 g
PROPYLPARABEN (UNII: Z8IX2SC1OH)	0.5 mg in 1 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	8 mg in 1 g
WATER (UNII: 059QF0KO0R)	717.8 mg in 1 g
YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69740-322-01	3.5 g in 1.0 PACKET; Type 0: Not a Combination Product	08/01/2005	
2	NDC:69740-322-00	114 g in 1.0 TUBE; Type 0: Not a Combination Product	08/01/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/01/2005	

Labeler - Smith & Nephew Medical Ltd (216344051)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(69740-322)

