

SECURA PROTECTIVE- petrolatum 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.

Secura Protective Ointment

DRUG FACTS

ACTIVE INGREDIENTS

Petrolatum 98.789%

PURPOSE

Skin Protectant

USES

- Skin protectant
- Helps treat and prevent diaper dermatitis
- Protects minor skin irritation associated with diaper dermatitis and helps seal out wetness

WARNINGS

- **For external use only**
- **Avoid contact with the eyes**

- **Not to be applied** over deep or puncture wounds, infections or lacerations

- **If condition worsens** or does not improve within 7 days, contact a doctor

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

- change wet and soiled diapers, garments and linens promptly
- cleanse the affected area and allow to dry
- apply ointment 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

benzyl alcohol, clove oil, o-phenylphenol, tocopheryl acetate, corn oil, retinyl palmitate, cholecalciferol, D&C Green #6

QUESTIONS OR COMMENTS?

1 800 876-1261

**PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA PROTECTIVE OINTMENT
(3.5 g)**

#59434800

NDC-69740-315-01

Protective Ointment

Skin Protectant

- For treatment and prevention of diaper dermatitis associated with exposure to feces or urine
- Contains Vitamins A, D & E
- Moisturizes and conditions
- Clove Oil controls odor
- Pediatrician tested

Smith&Nephew

Secura◊

Protective Ointment

Net wt. 0.12 oz (3.5 g)

Made in the USA for:

Smith & Nephew Medical Ltd,

101 Hessle Road, Hull, HU3 2BN, England

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SECURA[◊]

Protective Ointment

Net wt. .12 oz (3.5 g)

EAN GS1
 00369740315011

SECURA PROTECTIVE

petrolatum ointment

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69740-315 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 987.89 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | 5 mg in 1 g |
| CLOVE OIL (UNII: 578389D6D0) | 3 mg in 1 g |
| D&C GREEN NO. 6 (UNII: 4QP5U84YF7) | 0.01 mg in 1 g |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | 2 mg in 1 g |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | 0.1 mg in 1 g |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| CORN OIL (UNII: 8470G57WFM) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69740-315-01 | 3.5 g in 1 POUCH; Type 0: Not a Combination Product | 08/01/2003 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 08/01/2003 | |

Labeler - Smith & Nephew Medical Ltd (216344051)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| Swiss-American CDMO LLC | | 080170933 | MANUFACTURE(69740-315) |

Revised: 8/2017

Smith & Nephew Medical Ltd