

**SECURA PERSONAL SKIN CARE KIT- benzethonium chloride,petrolatum
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 Personal Skin Care Kit

☐#59434300

☐NDC 69740-343-00

☐Personal Skin Care Kit

Good skin care can help prevent breakdown

DIRECTIONS

1. Change wet and soiled diapers, garments, and linens promptly. Spray cleanser liberally on affected area.
2. Wipe clean with tissues, and remove soiled underpads and diapers.
3. Immediately dispose of tissues and underpads to control odor. Allow to dry. No rinsing necessary.
4. Apply protective 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.
5. Check patient often. Repeat steps 1-4 after each exposure to feces and urine.

Refer to individual product labeling for detailed instructions.

☐Packaged in the USA with products made in USA and India for:

Smith & Nephew Medical Ltd, 101 Hessle Road, Hull, HU3 2BN England.

www.smith-nephew.com

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DRUG FACTS - SECURA◇ PERSONAL CLEANSER

ACTIVE INGREDIENT

Benzethonium chloride 0.13%

PURPOSE

Antimicrobial

USES

- antimicrobial skin cleanser for the perineum or body
- aids in the removal of urine, feces, or other foreign material

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.** In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

- spray cleanser liberally on affected area, then wipe clean
- no rinsing necessary

INACTIVE INGREDIENTS

water, octoxynol-9, sodium citrate, polysorbate 20, propylene glycol, citric acid, diazolidinyl urea, polyquaternium-4, benzyl alcohol, methylparaben, fragrance, disodium EDTA, D&C Red #33

DRUG FACTS - SECURA◇ PROTECTIVE OINTMENT

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 PERSONAL SKIN CARE KIT

#59434300

NDC 69740-343-00

Personal Skin Care Kit

Kit contains:

Antimicrobial Skin Cleanser

SECURA◇ Personal Cleanser

8 fl. oz. (236 mL)

- No rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-balanced
- Pediatric tested
- CHG compatible

Skin Protectant

SECURA◇ Protective Ointment

2.47 oz. (70 g)

- For treatment and prevention of incontinence-associated dermatitis
- Enriched with Vitamins A, D & E
- Pediatric tested
- CHG compatible
- Enriched with Clove Oil

Smith&Nephew

Secura◇

□**Personal Skin Care Kit**



Personal Skin Care Kit

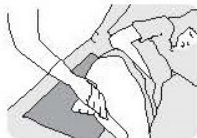
REF 59434300
NDC 69740-343-00

Personal Skin Care Kit

Good skin care can help prevent breakdown.



1. Change wet and soiled diapers, garments, and linens promptly. Spray cleanser liberally on affected area.



2. Wipe clean with tissues, and remove soiled underpads and diapers.



3. Immediately dispose of tissues and underpads to control odor. Allow to dry. No rinsing necessary.



4. Apply protective 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.



5. Check patient often. Repeat steps 1-4 after each exposure to feces and urine.

Refer to individual product labeling for detailed instructions.

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REF 59434300
NDC 69740-343-00

SECURA® Personal Cleanser

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride (1.13% Antimicrobial)	

Uses Antimicrobial skin cleanser for the perineum or body
Use in the removal of urine and feces, or other foreign material

Warnings
For external use only
Avoid contact with the eyes
Not to be applied over deep or punctate wounds, lacerations or incisions
If condition worsens or does not improve within 7 days, contact a doctor

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions Use spray cleanser liberally on affected area, then wipe clean
No rinsing necessary

Inactive Ingredients water, octagel-8, sodium citrate, polyacrylate 20, propylene glycol, stearic acid, diisodibutyl urea, polyquaternium-4, benzyl alcohol, methylparaben, fragrance, disodium EDTA, D&C Red #22

SECURA® Protective Ointment

Drug Facts

Active Ingredient	Purpose
Petrolatum 98.789% Skin protectant	

Uses Skin protectant
Helps treat and prevent diaper dermatitis
Prevents 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 punctate wounds, lacerations or incisions
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 Use change wet and soiled diapers, garments and linens promptly
Use on 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-phorylphenol, tocopheryl acetate, cove oil, ritanyl palmifata, cholecalciferol, D&C Green #8

Questions or comments?
1 800 876-1281

REF 59434300
NDC 69740-343-00

Personal Skin Care Kit

Kit contains:

Antimicrobial Skin Cleanser

SECURA® Personal Cleanser
8 fl. oz. (236 mL)

- No rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-balanced
- Pediatric tested
- CHG compatible

Skin Protectant

SECURA® Protective Ointment
2.47 oz. (70 g)

- For treatment and prevention of incontinence-associated dermatitis
- Enriched with Vitamins A, D & E
- Pediatric tested
- CHG compatible
- Enriched with Clove Oil



PACKAGE LABEL - SIDE DISPLAY PANEL - SECURA PERSONAL SKIN CARE KIT

#594343000

□NDC □69740-343-00

□Personal Skin Care Kit

Kit Contains:

Secura Personal Cleanser 8 fl. oz. (236 mL)

Secura Protective Ointment 2.47 oz. (70 g)

Smith & Nephew

Secura

Personal Skin Care Kit

59434300
NDC 69740-343-00

Personal Skin Care Kit

Kit contains:

SECURA Personal Cleanser

8 fl. oz. (236 mL)

SECURA Protective Ointment

2.47 oz. (70 g)



UNVARNISHED
AREA



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA PERSONAL CLEANSER (236mL)

#59430400

□NDC □69740-304-00

□**Personal Cleanser**

Antimicrobial Skin Cleanser

- No-rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-balanced
- Pediatric tested
- CHG compatible

Smith&Nephew

Secura◇

Personal Cleanser

8 fl oz. (236 mL)

DRUG FACTS

ACTIVE INGREDIENT

□Benzethonium chloride 0.13%

□**PURPOSE**

□Antimicrobial

□**USES**

- □antimicrobial skin cleanser for the perineum or body
- aids in the removal of urine, feces, or other foreign material

□**WARNINGS**

- □**For external use only**
- □**Avoid contact with 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.** □In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

□**DIRECTIONS**□

- spray cleanser liberally on affected area, then wipe clean
- no rinsing necessary

INACTIVE INGREDIENTS

water, octoxynol-9, sodium citrate, polysorbate 20, propylene glycol, citric acid, diazolidinyl urea, polyquaternium-4, benzyl alcohol, methylparaben, fragrance, disodium EDTA, D&C Red #33

QUESTIONS OR COMMENTS?

1 800 876-1261

Made in USA for:


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 101 Hessle Rd, Hull HU3 2BN England.
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REF 59430400
NDC 69740-304-00

Personal Cleanser

Antimicrobial Skin Cleanser

- No-rinse, one-step cleansing for perineum or body
- Gently removes urine, feces, and other body fluids
- Reduces odor
- pH-buffered
- Pediatric tested
- CHG compatible



SECURA[◇]
Personal Cleanser

8 fl. oz. (236 mL)

Drug Facts

Active ingredient	Purpose
Benzethonium chloride 0.13%	Antimicrobial

Uses

- antimicrobial skin cleanser for the perineum or body
- aids in the removal of urine and feces, or other foreign material

Warnings

For external use only

Avoid contact with 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. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Directions

- spray cleanser liberally on affected area, then wipe clean
- no rinsing necessary

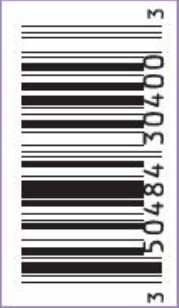
Inactive ingredients water, octoxynol-9, sodium citrate, polysorbate 20, propylene glycol, citric acid, diazolidinyl urea, polyquaternium-4, benzyl alcohol, methylparaben, fragrance, disodium EDTA, D&C Red #33

Questions or comments? 1 800 876-1261

Room #


Name

Made in USA for
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 and Tm. Off.



3 50484 30400 3

59763



PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA PROTECTIVE OINTMENT (70g)

#59431500
 NDC 69740-315-00

Protective Ointment

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- Enriched with Vitamins A, D & E
- Pediatric tested
- CHG compatible
- Enriched with Clove Oil

Smith&Nephew

Secura [◇]

Protective Ointment

Net wt. 2.47 oz (70g)

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

Made in India for:

Smith & Nephew Medical Ltd

101 Hessle Rd, Hull HU3 2BN England

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Drug Facts

Active ingredient	Purpose
Petrolatum 98.789%	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

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

Questions or comments? 1 800 876-1261

Made in India for 56297
Smith & Nephew Medical Ltd,
101 Hessle Rd, Hull HU3 2BN England.

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GO/DRUGS/361



Room #

Name

PO

REF 59431500

NDC 69740-315-00

Protective Ointment

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- Enriched with Vitamins A, D & E
- Pediatric tested
- CHG compatible
- Enriched with Clove Oil



SECURA[®]
Protective Ointment

Net wt. 2.47 oz. (70 g)

benzethonium chloride,petrolatum kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-343
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69740-343-00	1 in 1 CARTON; Type 0: Not a Combination Product	08/01/2003	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, SPRAY	236 mL
Part 2	1 TUBE	70 g

Part 1 of 2

SECURA PERSONAL CLEANSER

benzethonium chloride spray

Product Information

Item Code (Source)	NDC:69740-304
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1.3 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	2 uL in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	3.08 ug in 1 mL
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	3 uL in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	1 ug in 1 mL
METHYL PARABEN (UNII: A2I8C7HI9T)	1 ug in 1 mL
OCTOXYNOL 9 (UNII: 7JPC6Y25QS)	20 uL in 1 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	10 ug in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	10 uL in 1 mL
WATER (UNII: 059QF0KO0R)	929.389 uL in 1 mL
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	171.3 ug in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236 mL in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E		

Part 2 of 2**SECURA PROTECTIVE**

petrolatum ointment

Product Information

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		70 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

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

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-America Products, Inc.		080170933	manufacture(69740-304, 69740-343)

Establishment

Name	Address	ID/FEI	Business Operations
ENCUBE ETHICALS PVT LTD		915834105	manufacture(69740-315)

Revised: 12/2017

Smith & Nephew Medical Ltd