

SECURA STARTER 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 Starter Kit

#59434200

NDC 69740-342-00

Starter 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.
6. Moisturize skin daily and after bathing to prevent dryness.

Refer to individual product labeling for detailed instructions.

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DRUG FACTS - SECURA MOISTURIZING 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

WARNING

- **For external use only**
- **Avoid contact with eyes**
- **Not to be applied** over deep puncture wounds, infections, or lacerations.
- **If condition worsens** or does not improve within 7 days, consult a doctor.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

DIRECTIONS

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

INACTIVE INGREDIENTS

water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

DRUG FACTS - SECURA PROTECTIVE OINTMENT

ACTIVE INGREDIENT

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 STARTER KIT

#59434200

NDC 69740-342-00

Starter Kit

Kit Contains:

Antimicrobial Skin Cleanser

Secura Moisturizing 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-buffered
- 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

Moisturizer

Secura Moisturizing Cream

3 fl oz (85 g)

- Nourishes, hydrates and restores moisture to dry skin
- Enriched with Vitamin E
- Absorbs quickly, non-greasy
- Fortifies moisture balance
- Lanolin-free
- CHG compatible

Smith&Nephew

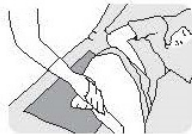


Starter Kit

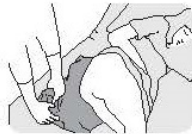
Good skin care can help prevent breakdown.



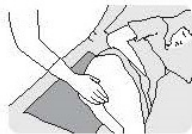
1. Change wet and soiled diapers, garments, and linens promptly. Spray cleanser liberally on affected area.



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.
6. Moisturize skin daily and after bathing to prevent dryness.

Refer to individual product labeling for detailed instructions.

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59434200
NDC 69740-342-00

SECURA[®] Moisturizing Cleanser

Drug Facts

Active Ingredient	Purpose
Benzalkonium chloride 0.12%	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, lacerations or abrasions
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
Apply cleanser liberally on affected area, then wipe clean
No rinsing necessary

Active Ingredients: water, polyorbide 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

SECURA[®] Protective Ointment

Drug Facts

Active Ingredient	Purpose
Petrolatum 86.785%	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, lacerations or abrasions
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

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

Questions or comments? 1 800 876-1281

59434200
NDC 69740-342-00

Starter Kit

Kit contains:

Antimicrobial Skin Cleanser

SECURA[®] Moisturizing 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-buffered
- 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

Moisturizer

SECURA[®] Moisturizing Cream 3 fl. oz. (85 g)

- Nourishes, hydrates and restores moisture to dry skin
- Enriched with Vitamin E
- Absorbs quickly, non-greasy
- Fortifies moisture balance
- Lanolin-free
- CHG compatible

smith&nephew
SECURA[®]
Starter Kit

PACKAGE LABEL - SIDE DISPLAY PANEL - SECURA STARTER KIT

#59434200

NDC 69740-342-00

Starter Kit

Kit contains

Antimicrobial Skin Cleanser

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

Skin Protectant

Secura Protective Ointment
2.47 oz. (70 g)

Moisturizer

Secura Moisturizing Cream
3 fl. oz (85 g)

Smith&Nephew
Secura
Starter Kit

REF 59434200

NDC 69740-342-00

Starter Kit

Kit contains:

Antimicrobial Skin Cleanser

SECURA[®] Moisturizing Cleanser
8 fl. oz. (236 mL)

Skin Protectant

SECURA[®] Protective Ointment
2.47 oz. (70 g)

Moisturizer

SECURA[®] Moisturizing Cream
3 fl. oz. (85 g)





UNVARNISHED
AREA

 **smith&nephew**
SECURA[®]
Starter Kit

**PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA MOISTURIZING CLEANSER
- BOTTLE (236 mL)**

Item #59430900

NDC 69740-309-00

Moisturizing 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

Moisturizing Cleanser

8 fl. oz. (236 mL)

DRUG FACTS - SECURA[®] MOISTURIZING 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 eyes**

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

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

- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately

DIRECTIONS

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

INACTIVE INGREDIENTS

water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

QUESTIONS OR COMMENTS?

1 800 876-1261

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101 Hessle Rd,

Hull HU3 2BN England.

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REF 59430900
NDC 69740-309-00

Moisturizing 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



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

Directions

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

Inactive ingredients water, polysorbate 20, glycerin, polyquaternium-10, benzyl alcohol, fragrance, disodium EDTA, aloe barbadensis, FD&C Blue #1

Questions or comments? 1 800 876-1261

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59857



Room #

Name

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

Item #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. (70 g)

DRUG FACTS

ACTIVE INGREDIENT

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

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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

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

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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, com oil, retinyl palmitate, cholecalciferol, D&C Green #6

Questions or comments? 1 800 876-1261

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GO/YDRUGS/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

 **smith&nephew**
SECURA[◇]
Protective Ointment

Net wt. 2.47 oz. (70 g)

SECURA STARTER KIT

benzethonium chloride, petrolatum kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-342
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69740-342-00	1 in 1 KIT	08/01/2003
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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 MOISTURIZING CLEANSER

benzethonium chloride spray

Product Information

Item Code (Source)	NDC:69740-309
Route of Administration	TOPICAL

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
ALOE VERA FLOWER (UNII: 575DY8C1ER)	0.05 ug in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	2 uL in 1 mL
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.001 uL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	10 uL in 1 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	30 ug in 1 mL
WATER (UNII: 059QF0K00R)	945.94 uL in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 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-American Products, Inc.		080170933	manufacture(69740-309, 69740-342)

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

Revised: 12/2017

Smith & Nephew Medical Ltd