

**SECURA TWO STEP KIT- benzethonium chloride and zinc oxide 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 Two Step Kit

#59434400

NDC 69740-344-00

Two-Step Kit

DIRECTIONS

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 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.
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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Certain marks reg'd U.S. Pat. & Tm. Off.

DRUG FACTS - SECURA◇ MOISTURIZING CLEANSER

ACTIVE INGREDIENTS

Benzethonium chloride 0.13%

PURPOSE

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

DRUG FACTS - SECURA◇ PROTECTIVE CREAM

ACTIVE INGREDIENTS

Zinc oxide 10%

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 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 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, cetearyl alcohol, PEG-40 castor oil, polysorbate 20, octyl palmitate, sodium cetearyl sulfate, octyl stearate, dioctyl adipate, tocopheryl acetate, methylparaben, allantoin, clove oil, o-phenylphenol, aloe barbadensis

QUESTIONS OR COMMENTS?

1 800 876-1261

PACKAGE LABEL (Front)

#59434400

NDC 69740-344-00

Two-Step 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 Cream

2.75 oz. (78g)

- For treatment and prevention of incontinence-associated dermatitis
- Pediatric tested
- CHG compatible
- Enriched with allantoin, Vitamin E and Aloe
- Clove Oil controls odor
- Conditions and soothes

smith&nephew

SECURA◇

Two-Step Kit

PACKAGE LABEL (Side)

Two-Step Kit

Kit contains:

SECURA◇ Moisturizing Cleanser

8 fl. oz. (236 mL)

SECURA◇ Protective Cream

2.75 oz. (78 g)

smith&nephew

SECURA◇

Two-Step Kit

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Two-Step Kit

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SECURA◇

NDC 69740-344-00

SECURA◇ Moisturizing Cleanser

REF 59434400
NDC 69740-344-00

Drug Facts	
Active Ingredient	Purpose
Benzalkonium chloride 0.12% Antimicrobial	
Uses - Antimicrobial skin cleanser for the perineum or body. It also is the removal of urine and feces, or other foreign material.	
Warnings	
For external use only.	
Avoid contact with eyes.	
Do not use on 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, polyorbata 20, glycerin, polyquaternium-10, benzyl alcohol, fragrances, disodium EDTA, also benzalkonium, PEG-15 Stearic Acid.	

Two-Step Kit

Good skin care can help prevent breakdown.



- Change wet and soiled diapers, garments, and liners promptly. Spray cleanser liberally on affected area.
- Wipe clean with tissues, and remove soiled underpads and diapers.
- Immediately dispose of tissues and underpads to control odor. Allow to dry. No rinsing necessary.
- Apply protective cream liberally as often as necessary with each diaper, garment, or linen change; especially at bedtime or anytime when exposure to soiled diapers, garments, liners, feces or urine may be prolonged.
- 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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Two-Step Kit

Kit contains:

- SECURA◇ Moisturizing Cleanser 8 fl. oz. (236 mL)
- SECURA◇ Protective Cream 2.75 oz. (78 g)

SECURA◇ Moisturizing Cleanser

REF 59434400
NDC 69740-344-00

Two-Step 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 Cream
2.75 oz. (78g)

- For treatment and prevention of incontinence-associated dermatitis
- Pediatric tested
- CHG compatible
- Enriched with Allantoin, Vitamin E and Aloe
- Clove Oil controls odor
- Conditions and soothes

Two-Step Kit

Kit contains:

- SECURA◇ Moisturizing Cleanser 8 fl. oz. (236 mL)
- SECURA◇ Protective Cream 2.75 oz. (78 g)



UNVARNISHED AREA

smith&nephew
SECURA◇
Two-Step Kit

PACKAGE LABEL - SECURA MOISTURIZING CLEANSER

Item #59430900

NDC 69740-309-00

**Moisturizing
Cleanser**

Antimicrobial Skin Cleanser

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

Smith&Nephew

Secura [◇]Moisturizing Cleanser

8 fl. oz. (236mL)

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 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

Made in USA for:

Smith & Nephew Medical Ltd

101, Hessle Rd,

Hull HU3 2BN England

www.smith-nephew.com

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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



SECURA[◇]
Moisturizing 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

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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

Room #

Name

Made in USA for
Smith & Nephew Medical Ltd,
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Hull HU3 2BN England.
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HDPE



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PACKAGE DISPLAY PANEL - SECURA PROTECTIVE CREAM

Item #59431200

NDC 69740-312-00

Protective Cream

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- Pediatric tested
- CHG compatible
- Enriched with Allantoin, Vitamin E and Aloe
- Clove Oil controls odor
- Conditions and soothes

Smith & Nephew
Secura[◇]Protective Cream

New wt. 2.75 oz. (78 g)

DRUG FACTS - SECURA PROTECTIVE CREAM

ACTIVE INGREDIENT

Zinc oxide 10%

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

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DIRECTIONS

- 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, cetearyl alcohol, PEG-40 caster oil, polysorbate 20, octyl palmitate, sodium cetearyl sulfate, octyl stearate, dioctyl adipate, tocopheryl acetate, methylparaben, allantoin, clove oil, o-phenylphenol, aloe barbadensis

QUESTIONS OR COMMENTS?

1 800 867-1261

Made in India for:

Smith & Nephew Medical Ltd,

101 Hessle Rd, Hull, HU3 2BN England.

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Drug Facts

Active Ingredient	Purpose
Zinc oxide 10%	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

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Directions

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- 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, cetearyl alcohol, PEG-40 castor oil, polysorbate 20, octyl palmitate, sodium cetearyl sulfate, octyl stearate, dioctyl adipate, tocopheryl acetate, methylparaben, allantoin, clove oil, o-phenylphenol, aloe barbadensis

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56306



GO/DRUGS/361



Room #

Name

REF 59431200
NDC 69740-312-00

Protective Cream

Skin Protectant

- For treatment and prevention of incontinence-associated dermatitis
- Pediatric tested
- CHG compatible
- Enriched with Allantoin Vitamin E and Aloe
- Clove Oil controls odor
- Conditions and soothes

 **smith&nephew**
SECURA[◊]
Protective Cream

Net wt. 2.75 oz. (78 g)

SECURA TWO STEP KIT

benzethonium chloride and zinc oxide cream kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69740-344
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69740-344-00	1 in 1 CARTON	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	78 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
BENZYL ALCOHOL (UNII: LKG8494WBH)	2 uL in 1 mL
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	0.001 ug in 1 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.2 ug in 1 mL
ALOE VERA FLOWER (UNII: 575DY8C1ER)	0.05 ug in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	10 ug in 1 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	30 ug in 1 mL
WATER (UNII: 059QF0KO0R)	945.94 uL 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	08/01/2003	

Part 2 of 2

SECURA PROTECTIVE

zinc oxide cream

Product Information

Item Code (Source) NDC:69740-312

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	597.125 mg in 1 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	89 mg in 1 g
ALLANTOIN (UNII: 344S277G0Z)	2 mg in 1 g
CLOVE OIL (UNII: 578389D6D0)	2 mg in 1 g
METHYLPARABEN (UNII: A2I8C7HI9T)	3 mg in 1 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	10 mg in 1 g
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	7 mg in 1 g
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	5 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U)	150 mg in 1 g
ALOE VERA FLOWER (UNII: 575DY8C1ER)	0.375 mg in 1 g
ETHYLHEXYL PALMITATE (UNII: 2865993309)	8 mg in 1 g
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	14 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		78 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	08/01/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part347	08/01/2003	
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Labeler - Smith & Nephew, Medical Ltd. (216344051)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-America Products, Inc.		080170933	manufacture(69740-309, 69740-344)

Establishment

Name	Address	ID/FEI	Business Operations
ENCUBE ETHICALS PVT LTD		915834105	manufacture(69740-312)

Revised: 12/2017

Smith & Nephew, Medical Ltd.