

SECURA MOISTURIZING CLEANSER- benzethonium chloride spray
Smith & Nephew, Inc.

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 Moisturizing Cleanser

DRUG FACTS

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

QUESTION OR COMMENTS?

1 800 876-1261

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL - SECURA MOISTURIZING CLEANSER (118mL)

Item #59430800
NDC 50484-308-00

Moisturizing Cleanser

Antimicrobial Skin Cleanser

- No-rinse, one-step cleansing for perineum or body
- Gentle surfactants emulsify stool without friction
- Reduces odor
- Non-irritating
- pH-balanced
- Contains Aloe and Glycerin to condition, soothe, and moisturize skin
- Pediatrician-tested

Smith&Nephew
Secura[◇]
Moisturizing Cleanser
4 fl. oz. (118mL)

Made for:
Smith & Nephew, Inc., St. Petersburg, FL 33716
www.smith-nephew.com
Trademark of Smith & Nephew. Reg. U.S. Pat. & Tm. Off.

Drug Facts

Active ingredient	Purpose
Benzethonium chlorides 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

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SS 02921



Room #

Name



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NDC 50484-309-00

Moisturizing

Cleanser

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Smith&Nephew

Secura[◇]

Moisturizing Cleanser

8 fl. oz. (236mL)

Made for:

Smith & Nephew, Inc., St. Petersburg, FL 33716

www.smith-nephew.com

Trademark of Smith & Nephew. Reg. U.S. Pat. & Tm. Off.

Drug Facts	
Active Ingredient	Purpose
Benzethonium chloride 0.13%	Antimicrobial
Uses	
<ul style="list-style-type: none"> ■ antimicrobial skin cleanser for the perineum or body ■ aids in the removal of urine and feces, or other foreign material 	
Warnings	
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Avoid contact with eyes	
Not to be applied over deep or puncture wounds, infections or lacerations	
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Room #

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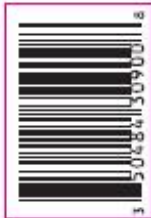
Item #59430900
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smith&nephew
SECURA[◇]
Moisturizing Cleanser

8 fl. oz. (236mL)

SECURA MOISTURIZING CLEANSER

benzethonium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50484-309
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0K00R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50484-309-00	236 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2003	12/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2003	12/31/2022

SECURA MOISTURIZING CLEANSER

benzethonium chloride spray

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GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50484-308-00	118 mL in 1.0 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2003	12/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2003	12/31/2022

Labeler - Smith & Nephew, Inc. (827731451)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(50484-309, 50484-308)

Revised: 7/2016

Smith & Nephew, Inc.