

BEDSIDE-CARE - benzethonium chloride shampoo
Coloplast Manufacturing US, LLC

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.

Bedside-Care[®] Unscented Foam
Bathing & Perineal Skin Cleanser
No-Rinse Foaming Body Wash, Shampoo & Incontinent Cleanser

For Full-Body Bathing And Perineal Clean-Up

Drug Facts

Active ingredient

Benzethonium Chloride 0.1%

Purpose

Antiseptic

Uses Protects against the risk of bacterial contamination in minor cuts, scraps and burns.

Warnings

When using this product: do not use in the eyes, with deep or puncture wounds, serious burns, or animal bites.

Stop using this product if:

- if skin irritation and redness develop
- if condition persists for more than 7 days, consult a physician.

For external use only.

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions Cleanse the affected area according to protocol.

Inactive ingredients purified water, sodium lauroamphoacetate, cocamidopropyl betaine, glycerin, polysorbate 20, quaternium-52, citric acid, quaternium-15, tetrasodium EDTA.

Protocol: Rinsing is not required. Aids in the removal of urine, feces and other foreign material.

Cleansing: apply to the affected area and remove with a moist washcloth. **Bathing:** dispense 3-4 pumps in a basin with warm water and cleanse the skin. **Shampooing:** pump foam directly on dampened hair, lather and remove with a moist washcloth.

Manufactured by: Coloplast A/S DK-3050 Humlebaek, Denmark

Distributed by: Coloplast Corp., Minneapolis, MN 55411 U.S.A.

1-800-533-0464 www.us.coloplast.com ©2007, Coloplast Corp.

Product #7146 Made in the U.S.A.

G7-1277

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 11701-053-04

Bedside-Care[®] Unscented Foam

Bathing & Perineal Skin Cleanser

No-Rinse Foaming
Body Wash, Shampoo
& Incontinent Cleanser

For Full Body
Bathing and Perineal
Clean-Up

Coloplast

4 fl. oz. (118 mL)

NDC 11701-053-04

Bedside-Care[®] Unscented Foam

Bathing & Perineal Skin Cleanser

No-Rinse Foaming
Body Wash, Shampoo
& Incontinent Cleanser

For Full Body
Bathing and Perineal
Clean-Up

Coloplast

4 fl. oz. (118 mL)

0123456789015

Drug Facts

Active ingredient	Purpose
Benzethonium Chloride 0.1 %	Antiseptic

Uses Protects against the risk of bacterial contamination in minor cuts, scrapes and bumps.

Warnings

When using this product: do not use in the eyes, with deep or puncture wounds, serious burns or animal bites.

Stop using this product: if skin irritation and redness develop ■ if condition persists for more than 7 days, consult a physician.

For external use only.

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions Cleanse the affected area according to protocol.

Inactive ingredients water, sodium lauroamphoacetate, cocamidopropyl betaine, glycerin, polysorbate 20, quaternium-52, citric acid, quaternium-15, tetrasodium EDTA

Protocol: Rinsing is not required. Aids in the removal of urine, feces and other foreign material. **Cleansing:** apply to the affected perineal area and remove with a moist washcloth. **Bathing:** dispense 3-4 pumps in a basin with warm water and cleanse the skin. **Shampooing:** pump foam directly on dampened hair, lather and remove with a moist washcloth.

Manufactured by: Coloplast A/S DK-3050 Humlebaek, Denmark
Distributed by: Coloplast Corp. Minneapolis, MN 55411 U.S.A.
1-800-633-0464 www.us.coloplast.com Product #7147
©2008-2, Coloplast Corp. Made in the U.S.A.

BB-1377

BEDSIDE-CARE

benzethonium chloride shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11701-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	100 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
QUATERNIUM-52 (UNII: 588EQF3HIP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-053-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/15/2009	
2	NDC:11701-053-05	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/15/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/15/2009	

Labeler - Coloplast Manufacturing US, LLC (110326675)

Registrant - Coloplast Corp (847436391)

Establishment

Name	Address	ID/FEI	Business Operations
Coloplast Manufacturing US, LLC		110326675	MANUFACTURE(11701-053)

Revised: 2/2018

Coloplast Manufacturing US, LLC