

BEDSIDE-CARE PERINEAL WASH - benzethonium chloride liquid
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® Perineal Wash

Perineal Skin Cleanser

No-Rinse

Incontinent Cleanser

For Perineal Clean-Up

Drug Facts

Active ingredient

Benzethonium Chloride 0.1%

Purpose

Antiseptic

Uses Protects against the risk of bacterial contamination in minor cuts, scrapes 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 skin irritation and redness develop
- if condition persists for more than 72 hours, consult a physician.

For external use only.

Keep this and all drugs out of the 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, citric acid, quaternium-52, quaternium-15, tetrasodium EDTA

Protocol: Shake well before use. **Cleansing:** Spray on the affected perineal area and remove with a moist washcloth. Aids in the removal of urine, feces and other foreign material. **Os tomy/Incontinence**

Appliance: To help control odor, spray into appliance before and after use.

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

Product #1453 ©2009-2, Coloplast Corp.

Made in the U.S.A.

B9-1383

PRINCIPAL DISPLAY PANEL - NET WT. 8 fl. oz. (237mL)

NDC 11701-059-05

Bedside-Care® Perineal Wash

Perineal Skin Cleanser

No-Rinse

Incontinent Cleanser

For Perineal Clean-Up

Coloplast

NET WT. 8 fl. oz. (237mL)


NDC 11701-059-04

Bedside-Care® Perineal Wash

Perineal Skin Cleanser

No-Rinse
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For Perineal
Clean-Up




4 fl. oz. (118 mL)

Patient's Name: _____

0 12345 67890 5

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B9-1382

Room # _____

BEDSIDE-CARE PERINEAL WASH

benzethonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11701-059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
QUATERNIUM-52 (UNII: 588EQF3HIP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM LAUROAMPHOACETATE (UNII: SLK428451L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11701-059-04	0.118 L in 1 BOTTLE, SPRAY		
2	NDC:11701-059-05	0.237 L in 1 BOTTLE, SPRAY		
3	NDC:11701-059-09	3.8 L in 1 BOTTLE		

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