

PERIFOAM- benzethonium chloride solution
Sage Pharmaceuticals, 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.

Perifoam™

Uses

PeriFoam™ is a safe, non-stinging foaming cleanser, which effectively kills odors and microorganisms on the skin, including the perineal area and around stoma sites and gastro-intestinal tube entry points. PeriFoam™ will not burn or cause discomfort on irritated or tender skin, but will gently soften and moisturize as it cleans.

Warnings

For external use only. Discontinue use ~ irritation and redness develop.

If condition persists for more than 48 hours, consult a doctor.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance.

Directions

For Perineal Area and Around Stoma Site

Spray PeriFoam™ on the perineal area or stoma site. Remove excess debris quickly. Spray PeriFoam™ again and gently wipe with water dampened cloth. Rinse with water:

For Gastro-Intestinal Tube Sites

Spray PeriFoam™ around the entry site. Gently clean with a damp cloth. Rinse with water. Repeat as necessary. After cleaning the area. Apply SkinSeal™ skin protectant around the site as directed by label.

Ingredients

Active Ingredient

Benzethonium Chloride, 0.2

Other Ingredients

purified water, non-ionic surfactants, fragrance, polyaminopropyl biguanide, aloe vera, dexpanthenol, disodium EDTA, and vitamin E.

Store between 59°-86° F (15-30°C)

Manufactured By:

Sage Pharmaceuticals, Inc.
Shreveport, LA 71109

PRINCIPAL DISPLAY PANEL - 237ml Bottle Label

NDC 59243-110-08

PeriFoam™

ANTI-BACTERIAL FOAMING CLEANSER

Active Ingredient: Benzethonium Chloride, 0.2%

REDUCES ODOR AND CONTAINS NO DYES

For foaming action, pull out tip of spray nozzle.

SHAKE WELL BEFORE USING

NET CONTENTS: 8 FL. OZ. (237ml)

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Warnings: For external use only. Discontinue use if irritation and redness develop. If condition persists for more than 48 hours, consult a doctor. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance.

Directions: **For Perineal Area and Around Stoma Site:** Spray PeriFoam™ on the perineal area or stoma site. Remove excess debris quickly. Spray PeriFoam™ again and gently wipe with warm dampened cloth. Rinse with water.

For Gastro-Intestinal Tube Sites: Spray PeriFoam™ around the entry site. Gently clean with a damp cloth. Rinse with water. Repeat as necessary. After cleaning the area, apply SkinSaa™ skin protectant around the site as directed by label.

Ingredients:
Active Ingredient: Benzethonium Chloride, 0.2%
Other Ingredients: purified water, non-ionic surfactants, fragrance, polyaminopropyl biguanide, aloe vera, dexpanthenol, disodium EDTA, and vitamin E.

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Lot #
Exp. Date

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Satisfaction Guaranteed

SAGE
Pharmaceuticals
SHREVEPORT, LA 71109

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PERIFOAM

benzethonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 243-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLOXAMER 188 (UNII: LQA7B6G8JG)	
POLYHEXANIDE (UNII: 322U039GMF)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHERSOLAN (UNII: O03S90U1F2)	

DECYL GLUCOSIDE (UNII: Z17H97EA6Y)

CAPRIC DIETHANOLAMIDE (UNII: SHH19DQ1DH)

EDETATE DISODIUM (UNII: 7FLD91C86K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59243-110-08	237 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	11/21/2000	

Labeler - Sage Pharmaceuticals, Inc. (626120919)

Revised: 8/2013

Sage Pharmaceuticals, Inc.