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.

PerifoamTM

Uses

PeriFoamTM 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 paints. PeriFoamTM will not bum 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 PeriFoamTM around the entry site. Gently clean with a damp cloth. Rinse with water. Repeat as necessary. After cleaning the area. Apply SkinSealTMskin protectant around the site as directed by label.

Ingredients

Active Ingredient

Benzethonium Chloride, 0.2

Other Ingredients

purified water, non-ionic surtactants, 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

PeriFoamTM

ANTI-BACTERIAL FOAMING CLEANSER

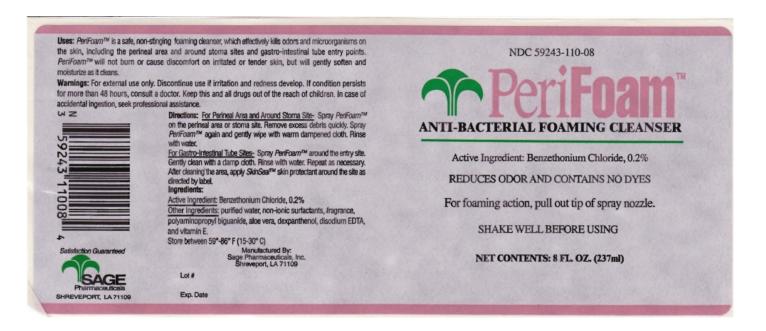
Active Ingredient: Benzethonium Chloride, 0.2%

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)



PERIFOAM

benzethonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59243-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZETHO NIUM CHLO RIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	2 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
POLOXAMER 188 (UNII: LQA7B6G8JG)		
POLIHEXANIDE (UNII: 322U039 GMF)		
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
TOCOPHERSOLAN (UNII: O03S90U1F2)		

DECYL GLUCO SIDE (UNII: Z17H97EA6Y)	
CAPRIC DIETHANO LAMIDE (UNII: SHH19 DQ 1DH)	
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)	

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.