

SEPTICARE- 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.

Septicare™

Drug Facts

Active Ingredient

Benzethonium Chloride 0.2%

Purpose

Antiseptic

Uses

For skin irritation due to incontinence. 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 right away.

Directions

Adjust nozzle to spray or stream setting. Spray/stream Septicare directly into wound, or soak gauze pad and pack the wound. Cover with secondary dressing of choice. Change dressing as needed, no rinsing necessary.

Inactive Ingredients

water, sodium chloride 0.9%, nonionic surfactant, biguanide.

Store at controlled room temperature between 50°F (10°C) and 86°F (30°C).

Protocol: Shake before use. Cleaning: Spray on the affected peritoneal area and remove with a moist washcloth. Aides in the removal of urine feces and other foreign material.

Manufactured by:

SAGE

PHARMACEUTICALS
5408 Interstate Drive
Shreveport, LA 71109

PRINCIPAL DISPLAY PANEL - 240 mL Bottle Label

NDC 59243-100-08

SeptiCare™

Wound Cleanser and Deodorant

Antiseptic

Saline based • No-rinse • Non-toxic • Non-stinging

Net Contents: 8 fl.oz. (240 mL)

Patient's Name:

NDC 59243-100-08



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Room #

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5408 Interstate Drive
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Lot #



1-318-635-4000
Reorder# TW9206-8

Exp. Date:

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SEPTICARE

benzethonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59243-100
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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
POLOXAMER 188 (UNII: LQA7B6G8JG)	
POLYHEXANIDE (UNII: 322U039GMF)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59243-100-08	240 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	06/26/1999	

Labeler - Sage Pharmaceuticals, Inc. (626120919)

Revised: 8/2013

Sage Pharmaceuticals, Inc.