

NOVANA WASH PERINEAL SKIN CLEANSER - benzethonium chloride solution
NOVANA MEDICAL 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.

Drug Facts

Active ingredient	Purpose
Benzethonium Chloride 0.1 %.....	Antiseptic

Uses For skin irritation due to incontinence. Protects against the risk of bacterial contamination in minor cuts, scrapes, and burns. Aids in the cleanup of urine and feces. Helps to remove barrier cream from skin.

Warnings

For external use only.

When using this product • Do not get into eyes. • If contact occurs, rinse eyes thoroughly with water.
Stop use and ask doctor if • if skin irritation and redness develop.

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 Cleanse the affected area according to protocol.

Inactive ingredients Water, Sodium Laureth Sulfate, Polyquaternium-7, Phenoxyethanol, Iodopropynyl Butylcarbamate

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

NDC 76077-100-04



**Perineal
Skin Cleanser**

No-rinse
body wash, shampoo
& incontinence cleanser



4 fl oz. (120 mL)e

Patient's Name:

Room:

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Other Information? • Store at room temperature 15°-30°C (59°-86°F).

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Questions or Comments? Call: 1-855-229-2031

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NOVANA WASH PERINEAL SKIN CLEANSER

benzethonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76077-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzethonium Chloride (UNII: PH41D05744) (Benzethonium - UNII:1VU15B70BP)	Benzethonium Chloride	0.001 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium Laureth Sulfate (UNII: BPV390UAP0)	
POLYQUATERNIUM-7 (76/24 ACRYLAMIDE/DADMAC; 120 KD) (UNII: AAJ238UT03)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:76077-100-04	120 mL in 1 BOTTLE, SPRAY		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	04/04/2012		

Labeler - NOVANA MEDICAL LLC (964916600)

Registrant - O.L. PRODUCTS, INC. (961405883)

Establishment

Name	Address	ID/FEI	Business Operations
O.L. PRODUCTS, INC.		961405883	label, manufacture

Revised: 4/2012

NOVANA MEDICAL LLC