BERBEREX WOUND CLEANSER- allantoin, benzethonium chloride solution
Cosmetic Specialty Labs, 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.

ACTIVE INGREDIENT

- Allantoin 0.5%
- Benzethonium Chloride 0.1%

PURPOSE

- Skin Protectant
- Antiseptic

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a poison control center immediately.

USES

helps protect skin and supports healing of minor cuts,

scapes, bums and wounds, including pressure sores, diabetic

ulcers, cracked skin and lips. topical antiseptic to help decrease

the risk of skin infections

WARNINGS

for external use only

Do not use

in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious bums

Stop use and ask a doctor if

- condition worsens
- symptoms perist for more than 7days or clear up and occur again within a few days

DIRECTIONS

Adults and children 2years of age and older

Use to clean minor cut, scrapes and burns by thoroughly flushing the affected area; let air dry; cover with adhesive bandage or sterile gauze; apply a small amount of this product on the area 1 to 3 times daily

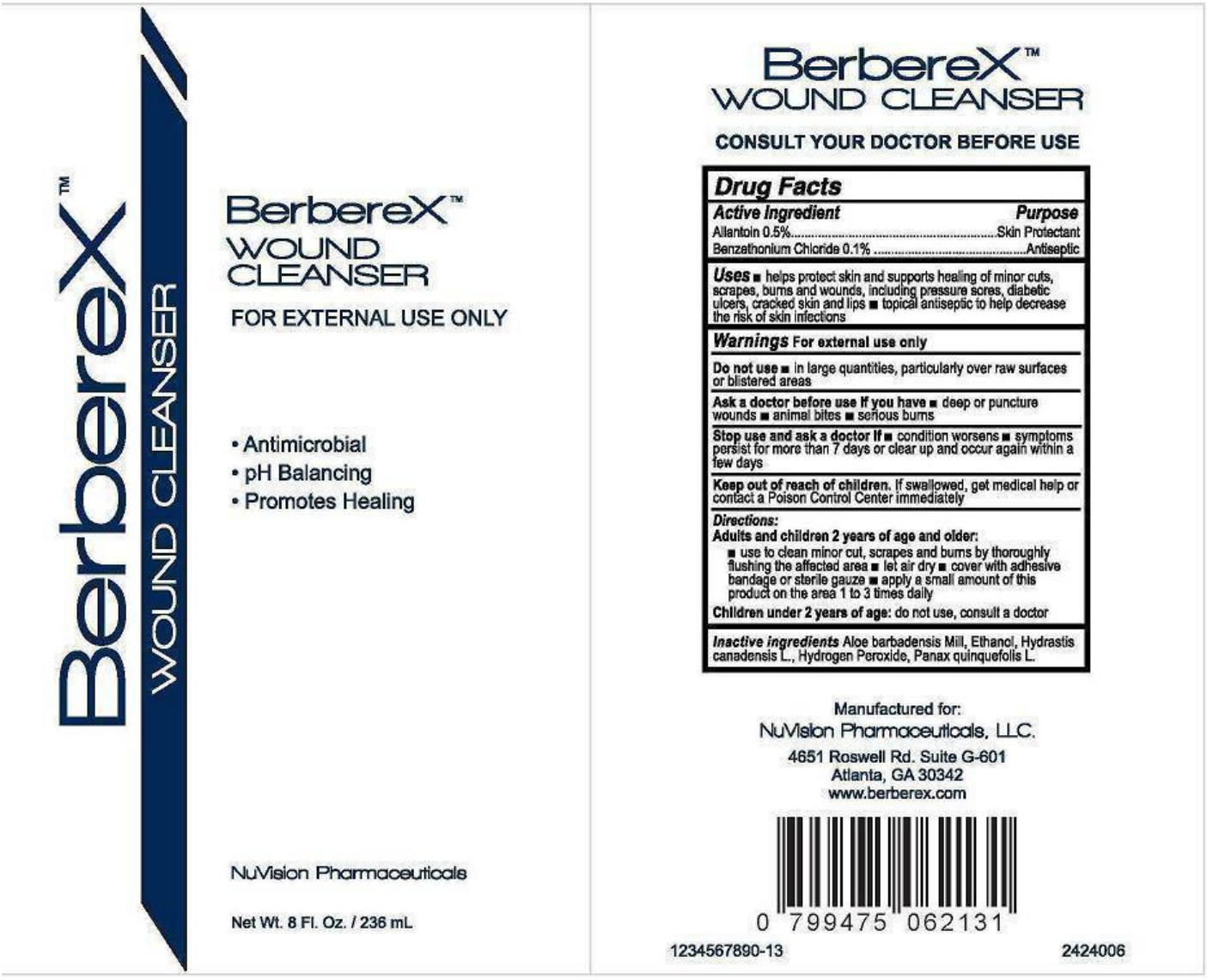
Children under 2years of age

do not use, consult a doctor

INACTIVE INGREDIENTS

Aloe barbadensis Mill, Ethanol, Hydrastis canadensis L., Hydrogen Peroxide, Panax quinquefolis L.

PRINCIPAL DISPLAY PANEL



BERBEREX WOUND CLEANSER

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	5 g in 1000 mL
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
ALCOHOL (UNII: 3K9958V90M)	
HYDRASTIS CANADENSIS WHOLE (UNII: R763EBH88T)	
Hydrogen Peroxide (UNII: BBX060AN9V)	
PANAX QUINQUEFOLIUS WHOLE (UNII: 0P067WOA1X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-055-04	118 mL in 1 BOTTLE		
2	NDC:58133-055-08	236 mL in 1 BOTTLE		
3	NDC:58133-055-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/15/2013	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty labs, Inc.		032973000	manufacture(58133-055)

Revised: 1/2014 Cosmetic Specialty Labs, Inc.