BACTINE MAX- benzalkonium chloride and lidocaine hydrochloride liquid
WellSpring Pharmaceutical Corporation

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.

Bactine® Max Pain Relieving Cleansing Spray

Drug Facts

Active ingredients	***Purpose***
Benzalkonium Cl 0.13% w/w	First aid antiseptic
Lidocaine HCl 4% w/w	Pain relieving spray

Uses

first aid to help prevent bacterial contamination or skin infection, and for temporary relief of pain and itching associated with minor:

- cuts
- scrapes
- minor burns
- sunburn
- minor skin irritations

Warnings

For external use only

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

When using this product

- do not use in or near the eyes
- do not apply over large areas of the body or in large quantities
- do not apply over raw surfaces or blistered areas

Stop use and ask a doctor if

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 2 years and older: clean the affected area; apply a small amount on the area 1-3 times daily; may be covered with a sterile bandage (let dry first)
- children under 2 years, ask a doctor

Other information

avoid excessive heat

Inactive ingredients

edetate disodium, fragrances, propylene glycol, purified water

Questions?

1-844-241-5454 Mon-Fri (8-5 EST) or www.bactine.com

Money Back Guarantee

Manufactured for: WellSpring, Sarasota, FL 34243

*germs commonly associated with skin infections.

PRINCIPAL DISPLAY PANEL - 148 mL Bottle Label

First Aid Pain Reliever & Antiseptic

Kills 99% of Germs*

Max Strength Germ Killing

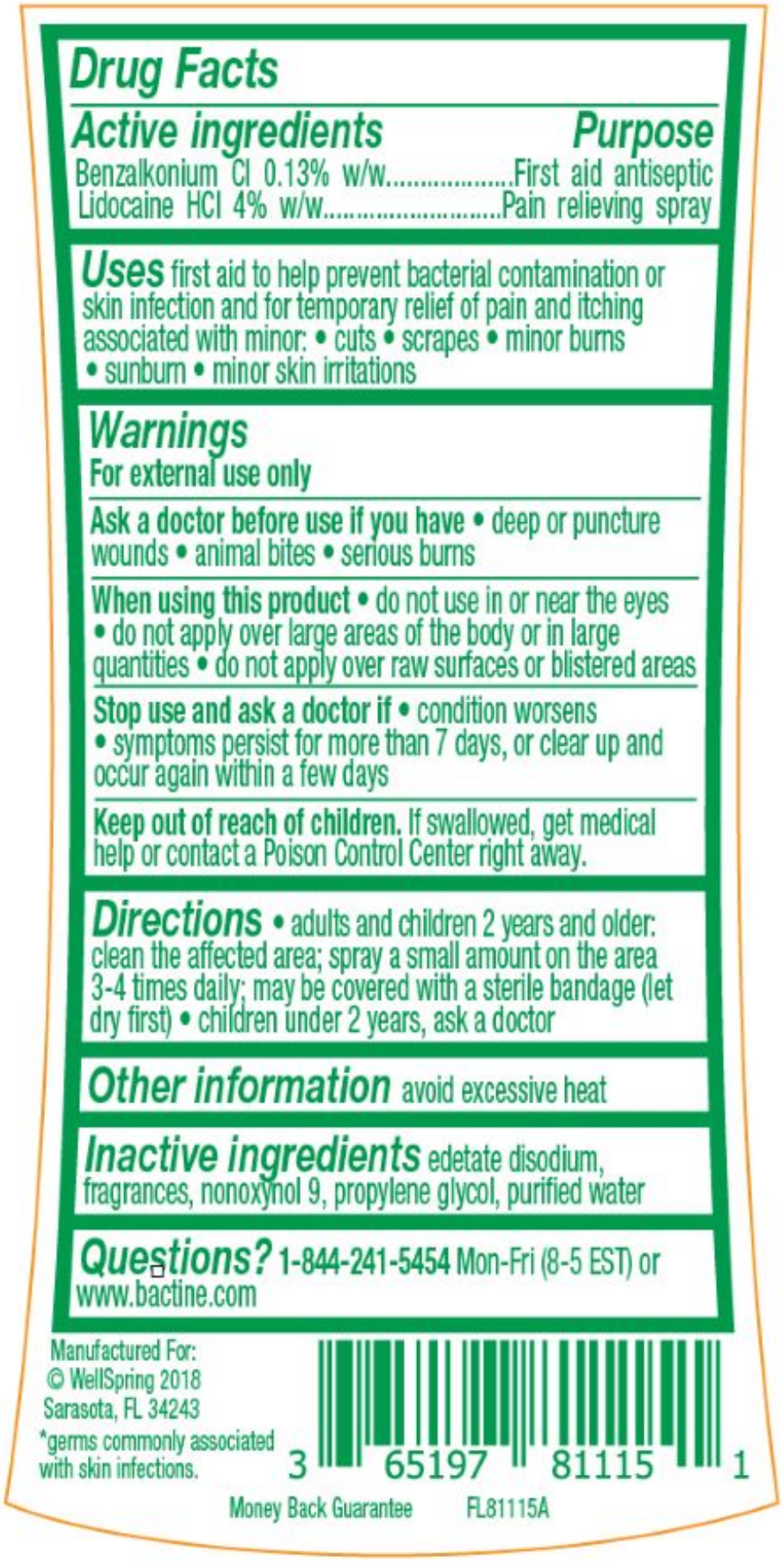
4% Lidocaine HCL

Max Strength Pain Reliever

No Sting

5 FL OZ (148 mL)

DRUG FACTS LABEL



PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

First Aid Pain Reliever & Antiseptic

Kills 99% of Germs*

Max Strength Germ Killing

4% Lidocaine HCL

Max Strength Pain Reliever

No Sting

4 FL OZ (118 mL)

Rear Label

BACTINE MAX

benzalkonium chloride and lidocaine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65197-811
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

EDETATE DISODIUM (UNII: 7FLD91C86K)	
NONOXYNOL-9 (UNII: 48Q180SH9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65197-811-15	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2018	
2	NDC:65197-811-14	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2018	

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 2/2021 WellSpring Pharmaceutical Corporation