FIRST AID ANTISEPTIC PAIN RELIEVING- benzalkonium chloride,pramoxine hydrochloride spray
Shandong Ruian Pharmaceutical Co.,Ltd.

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.

BENZALKONIUM CHLORIDE;
PRAMOXINE HYDROCHLORIDE;

First aid antibiotic
Topical analgesic

first aid to help prevent infection and for the temporary relief of pain or discomfort in minor:
• cuts
• scrapes
• burns

For external use only

• in the eyes
• over large areas of the body

• deep or puncture wounds
• animal bites
• serious burns

• condition or symptoms get worse or last more than one week
• symptoms 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 Centre right away.

• Adults and children 2 years of age and older:
• Clean the affected area
• Spray a small amount of this product on the area 1 to 3 times daily.
• May be covered with a sterile bandage
• If bandaged, let dry first
• Children under 2 years of age: consult a doctor

Store at Room Temperature

Water, Propylene Glycol, Edetate Disodium

If swallowed, get medical help or contact a Poison Control Center right away.

NDC: 82199-610-26 7.7ml in 1 Vial

FIRST AID ANTISEPTIC PAIN RELIEVING

benzalkonium chloride,pramoxine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82199-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82199-610-26	7.7 mL in 1 VIAL; Type 0: Not a Combination Product	11/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/19/2021	

Labeler - Shandong Ruian Pharmaceutical Co.,Ltd. (723845363)

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