KEEPAN A- benzalkonium chloride, lidocaine hydrochloride spray
Sato 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.

Keepan A

Active ingredients
Benzalkonium chloride 0.1%
Lidocaine hydrochloride 1%

Purpose
Benzalkonium chloride First aid antiseptic
Lidocaine hydrochloride External analgesic

Uses First aid for minor cuts, scrapes and burns:
■ to help reduce the risk of infection
■ for the temporary relief of pain and itching

Warnings
For external use only

Do not use
■ in the eyes ■ in large quantities
■ over large areas of the body ■ over raw surfaces or blistered areas
■ longer than 1 week unless directed by a doctor

Ask a doctor before use if you have
■ deep or puncture wounds ■ animal bites ■ serious burns

When using this product
■ avoid contact with the eyes

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
■ irritation, redness, swelling or pain persists or increases or a rash or infection develops

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 of age and older:
■ clean the affected area
■ spray a small amount directly on the affected area or apply with clean gauze or cotton saturated with KEEPAN A 1 to 3 times daily
■ may be covered with a sterile bandage
■ if bandaged, let dry first
Children under 2 years of age: Do not use, consult a doctor.

Inactive ingredients alcohol, fragrance, hydrochloric acid, purified water, sodium chloride, sodium citrate

KEEPAN A

benzalkonium chloride, lidocaine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49873-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-019-01	1 in 1 CARTON	07/15/1981	
1		60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/1981	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-019) , label(49873-019) , pack(49873-019)

Revised: 12/2020 Sato Pharmaceutical Co., Ltd.