

LEVIGOSP- lidocaine/benzalkonium chloride spray spray
Topicare Management, 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.

Description

LevigoSP is a Lidocaine HCL 2.5% and Benzalkonium Chloride 0.13% topical anesthetic and antiseptic spray indicated to temporarily relieve minor pain.

Active Ingredients

Lidocaine HCL 2.5% --- Pain Reliever

Benzalkonium Chloride 0.13% --- First Aid Antiseptic

Purpose

For the temporary relief of minor pain or discomfort associated with minor: cuts, scrapes, burns, sunburn, skin irritations. First aid to prevent bacterial contamination or skin infections.

Warnings

For external use only.

Ask Doctor

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

When Using This Product

When using this product: *use only as directed *do not use in or near the eyes *do not apply over large areas of the body *do not apply over raw surfaces or blistered areas.

Stop Use

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

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

Indications & Usage

Directions:

Adults and Children over 2 years: Clean the affected area, apply a small amount on the affected area 1 to 3 times daily. If bandaged, let dry first.

Children under 2 years: Ask a doctor.

Pregnant or breast feeding: Ask a doctor.

Dose & Administration

Manufactured By:

Wisconsin Pharmacal Co.

1 Pharmacal Way

Jackson, WI 53037

Made in the U.S.A. of U.S. and imported materials.

Net Wt. 8 FL OZ (240mL) bottle

Questions or Comments

For questions or comments, call 1-800-635-3696.

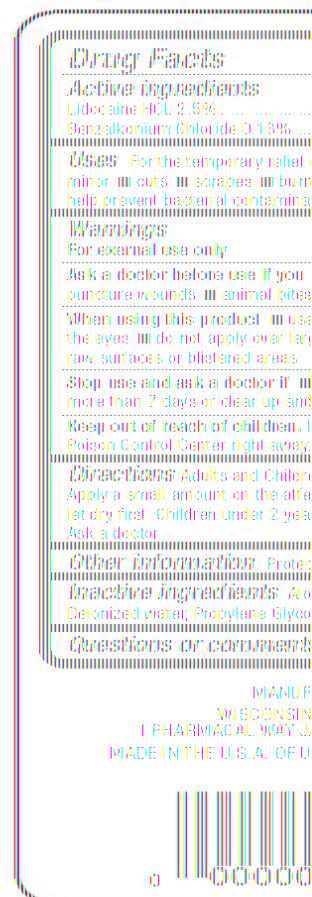
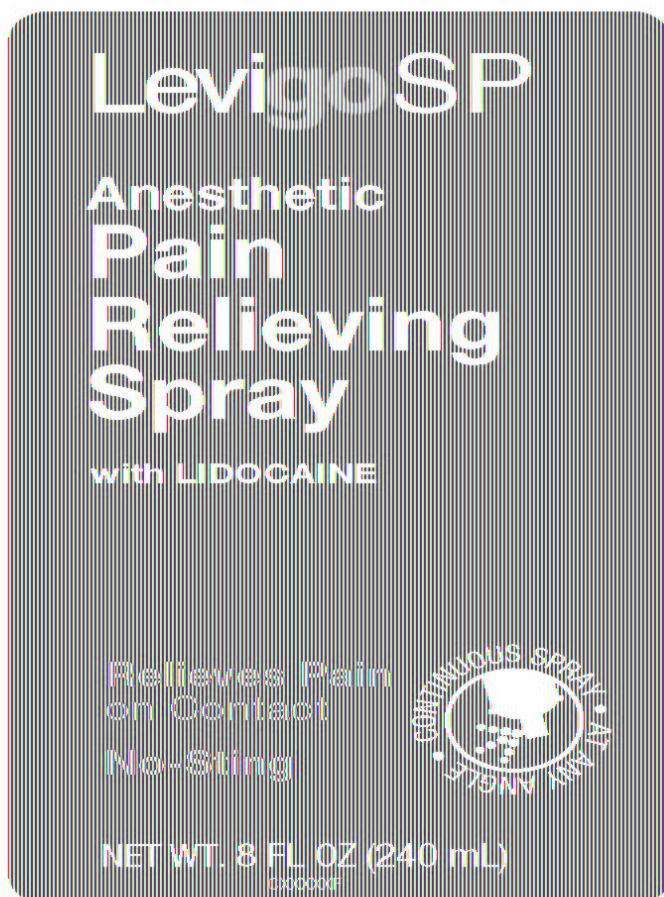
Inactive Ingredients

Aloe Barbadensis Leaf Juice, Camphor, Deionized water, Propylene Glycol

Storage & Handling

Protect from excessive heat.

Package Label. Principal Display Panel



LEVIGOSP

lidocaine/benzalkonium chloride spray spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70 112-155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.5 mg in 1 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70 112-155-08	240 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2018	

Labeler - Topicare Management, LLC (079902303)

Establishment

Name	Address	ID/FEI	Business Operations
Topicare Management, LLC		079902303	label(70112-155)

Establishment

Name	Address	ID/FEI	Business Operations
Wisconsin Pharmacal Company, LLC		800873986	manufacture(70112-155)

Revised: 2/2018

Topicare Management, LLC