

**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 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.

Manufactured For:

Topicare Therapeutics

1925 Longmire Rd.

Bldg. 2

Conroe, TX 77304

Net Wt. 5 FL OZ (150ml) bottle

**Questions or Comments**

For questions or comments, call 1-936-703-5474.

**Inactive Ingredients**

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
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 1 mL
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2.5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>CAMPHOR (NATURAL)</b> (UNII: N20HL7Q941)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70 112-155-05	150 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/19/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/19/2018	

**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: 8/2018

Topicare Management, LLC