DOLOGESIC ROLL-ON- lidocaine hcl liquid
Llorens Pharmaceutical International Division, Inc.

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.

Active Ingredient

Lidocaine HCL, USP 4%

Purpose

Topical Anesthetic

Use

Temporarily relieves minor pains

Warnings

For external use only

Do not use

- on large areas of the body or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this label.
- do not allow contact with eyes
- do not bandage or apply local heat (such as heating pads) to the area of use.

Stop use and ask doctor if

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

If pregnant or breast-feeding, ask a doctor before use.

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

Directions

- Adults and children over 12 years of age
- Apply generously to the affected area as needed every 6-8 hours, not to exceed 3 application in a 24 hour period.
- Not for use in children under 12 years of age.

Inactive ingredients

camphor, glycerin, isopropyl alcohol, menthol, methylparaben, propylparaben, purified water and xantham gum.

Questions

Llorens Pharmaceutical International Division, Inc.

Miami Fl 33147

DOLOGESIC ROLL-ON

lidocaine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-513
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-513-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2018	

Labeler - Llorens Pharmaceutical International Division, Inc. (037342305)

Revised: 12/2020 Llorens Pharmaceutical International Division, Inc.