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

- Iuse 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.

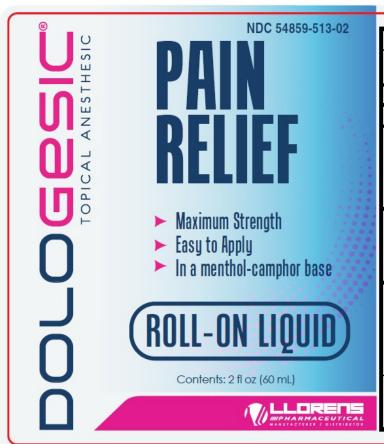
Inactive ingredients

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

Questions

Llorens Pharmaceutical International Division, Inc.

Miami Fl 33147



Drug Facts

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Manufactured by: Code#L-90 Rev.:02/18 Uorens Pharmaceutical International Division, Inc. Miami, FL 33147

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For lot number and expiration date, see top of cap. 3

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
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	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: 059QF0KOOR) 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 Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fi	nal part348	05/01/2018		

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

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