AMINO RIP MUSCLE PAIN RELIEF- lidocaine hcl liquid
LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION

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 Ingredients

Lidocaine HCl

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 direct. 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 the reach of children
- If swallowed, get medical help or contact a Poison Control Center right away.

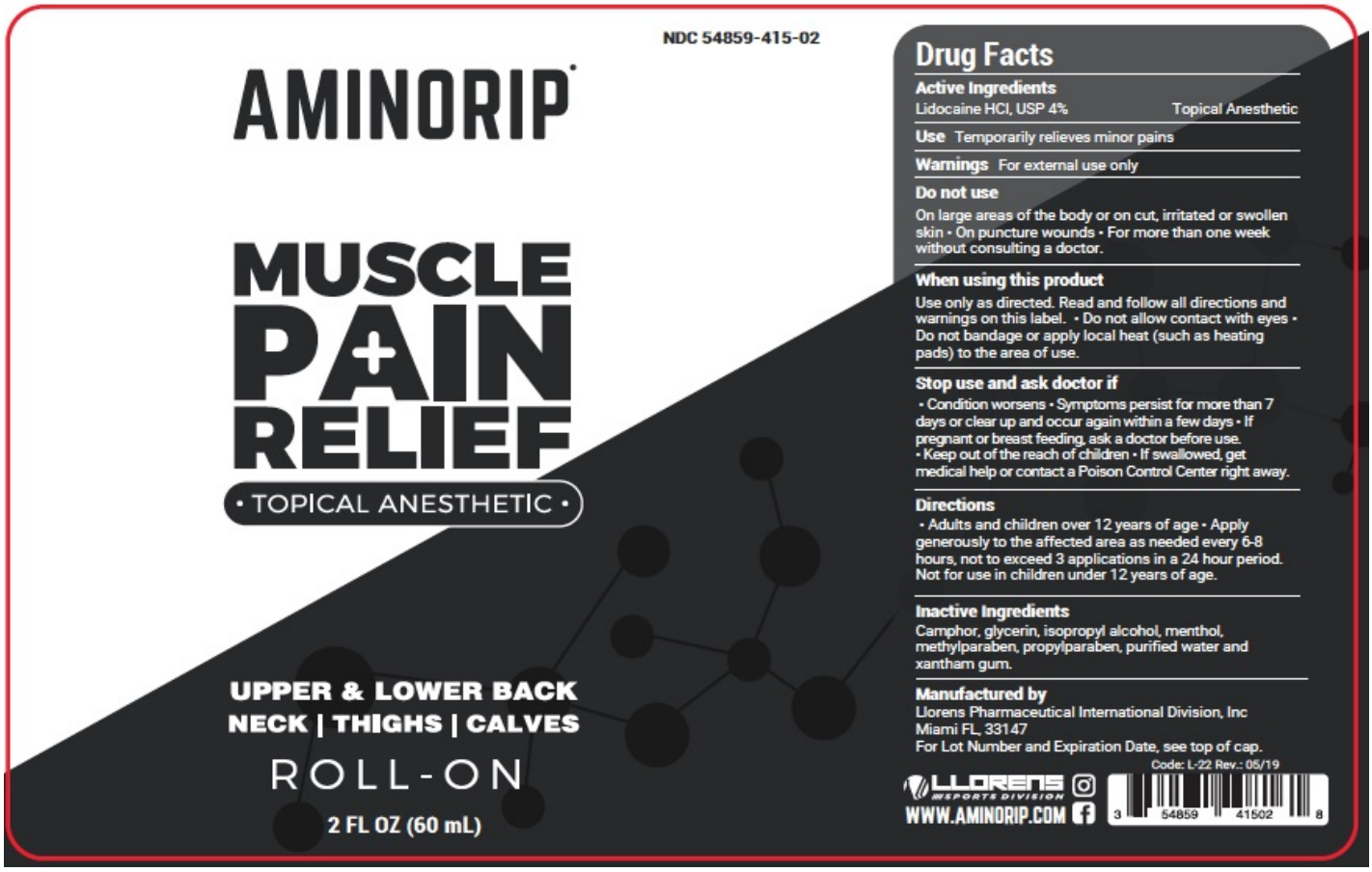
Keep out of reach of children.

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 applications 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, xantham gum



AMINO RIP MUSCLE PAIN RELIEF

lidocaine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-415
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 mg 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:54859-415-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	10/01/2019	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Registrant - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Establishment			
Name	Address	ID/FEI	Business Operations
LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION		037342305	manufacture(54859-415)

Revised: 10/2019 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION