PAIN RELIEF ROLL-ON- lidocaine hcl gel
Product Quest Mfg

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.

Scherer Labs

Drug Facts

Active ingredient	**Purpose**
Lidocaine HCl 4%.....	Topical anesthetic

Uses For temporary relief of pain and itching

Warnings
For external use only.
When using this product • use only as directed • avoid contact with eyes • do not use in large quantities, particularly over raw surfaces or blistered areas.
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. If swallowed, get medical help or contact a Poison Control Center immediately

Directions
Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
Children under 2 years of age: consult a doctor.

Inactive ingredients
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, C30-45 Alkyl Cetearyl Dimethicone Crosspolymer, Caprylyl Methicone, Cetearyl Alcohol, Ceteth-20 Phosphate, Dicetyl Phosphate, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Glyceryl Stearate, Methylparaben, SD Alcohol 40, Steareth-21, Water.

Scherer labs™

Max Strength Lidocaine

Pain Relief Roll-on Gel

Scherer labs™

Max Strength Lidocaine

Pain Relief Roll-on Gel

4% Lidocaine HCl

Topical Analgesic

Easy to roll-on, no-touch applicator

Temporary relief of pain

Helps pain-affected areas without irritation

Fragrance free

NET WT
2.5 OZ (71 g)

ACTUAL SIZE

PAIN RELIEF ROLL-ON

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64048-3333
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
Ceteth-20 Phosphate (UNII: 921FTA1500)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
Dimethicone (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Methylparaben (UNII: A2I8C7HI9T)	
ALCOHOL (UNII: 3K9958V90M)	
Steareth-21 (UNII: 53J3F32P58)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64048-3333-3	74 mL in 1 CONTAINER; Type 0: Not a Combination Product	09/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2017	

Labeler - Product Quest Mfg (927768135)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(64048-3333) , label(64048-3333)