

QC LIDOCAINE MAXIMUM STRENGTH- lidocaine hcl cream
Chain Drug Marketing Association

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.

Quality Choice Lidocaine Cream

Active Ingredient

Lidocaine HCl 4%

Purpose

Topical analgesic

Uses

temporarily relieves pain and itching due to:

minor burns

sunburn

minor cuts

scrapes

insect bites

minor skin irritations

Warnings

For external use only

Do not use

Do not use in large quantities, particularly over raw surfaces or blistered areas

When using this product

When using this product do not get into eyes

Stop use and ask a doctor if

condition gets worse

symptoms last for more than 7 days

symptoms 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 right away.

Directions

adults and children 2 years and over: apply to affected area not more than 3 to 4 times daily

children under 2 years: ask a doctor

Other information

store between 20 °C and 25 °C

Inactive ingredients

acrylates/C10-30 alkyl acrylate crosspolymer, aloe barbadensis (aloe vera) leaf juice, aminomethyl propanol, C30-45 alkyl cetearyl dimethicone crosspolymer, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, dicetyl phosphate, dimethicone, edetate disodium, ethylhexylglycerin, glyceryl monostearate, methylparaben, purified water, SD alcohol 40, steareth-21

Princippal display panel

Quality Choice

Maximum Strength Lidocaine Cream Lidocaine HCL 4 %- Topical Analgesic

Steroid free, Works on Contact

10/27/2019





Made in the U.S.A.

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NOTE TO OUR CUSTOMERS:
 When viewing proof with Acrobat always activate "Overprint Preview"
 Preferences / General / Page Display / Use Overprint Preview / Always

Job: 380022

Item Code: 157066

CAD Number: 24936A

Dimensions: W: 7.063 x H: 10.719

Inks: Cyan Magenta Yellow Black Cut crease Outside Bleed Glue/No coat area

Proof Date: 10/27/2019 12:39:20 PM

QC LIDOCAINE MAXIMUM STRENGTH

lidocaine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-956
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 g

Inactive Ingredients

Ingredient Name	Strength
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STEARETH-21 (UNII: 53J3F32P58)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETETH-20 PHOSPHATE (UNII: 921FTA1500)
ALCOHOL (UNII: 3K9958V90M)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
WATER (UNII: 059QF0KO0R)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
DIMETHICONE (UNII: 92RU3N3Y1O)
METHYLPARABEN (UNII: A2I8C7HI9T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-956-01	1 in 1 CARTON	12/07/2020	
1		49.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/07/2020	

Labeler - Chain Drug Marketing Association (011920774)

Registrant - Weeks & Leo Co., Inc. (005290028)

Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	manufacture(63868-956)