RUGBY LIDOCAINE- lidocaine cream
Rugby Laboratories

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.

Drug Facts

Active ingredient

Lidocaine HCL 4%

Purpose

Topical anesthetic

Uses

- Temporarily relieves minor pain

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 consultanting a doctor

When using this product

use only as directed. read and follow all directions and warnings on this carton.

do notallow contact with the eyes

do not bandage or apply local heat (such as heating pads) to the area of use.

Stop use and ask a doctor if

- condition worsens
- symptons persist for more than 7 days or clear up and occur again within a few days.
- **If pregnant or breast feeding**, ask a health professional before use.

Keep this and all drugs out of the reach of children and pets.

If swallowed, get medical help or contact Poison Control Center right away.

Directions

- **Adults and children over 12 years:**
- apply a thin layer ot affected area every 6 t o8 hours, not to exceed 3 applications in a 24 hour period
- **Children under 12 years or younger:** ask a doctor

Other information

- Store at controlled room temperature 20°-25°C (68°-77°F)

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, Phenoxyethanol, SD Alcohol 40, Steareth-21, Water (purified)

Questions?(800)645-2158

Principal Panel-Tube

RUGBY® NDC 0536-1139-20

Maxium Strength

4% Lidocaine

Pain Relieving Cream

NET WT. 15g (0.52 oz)

Principal Panel - Carton

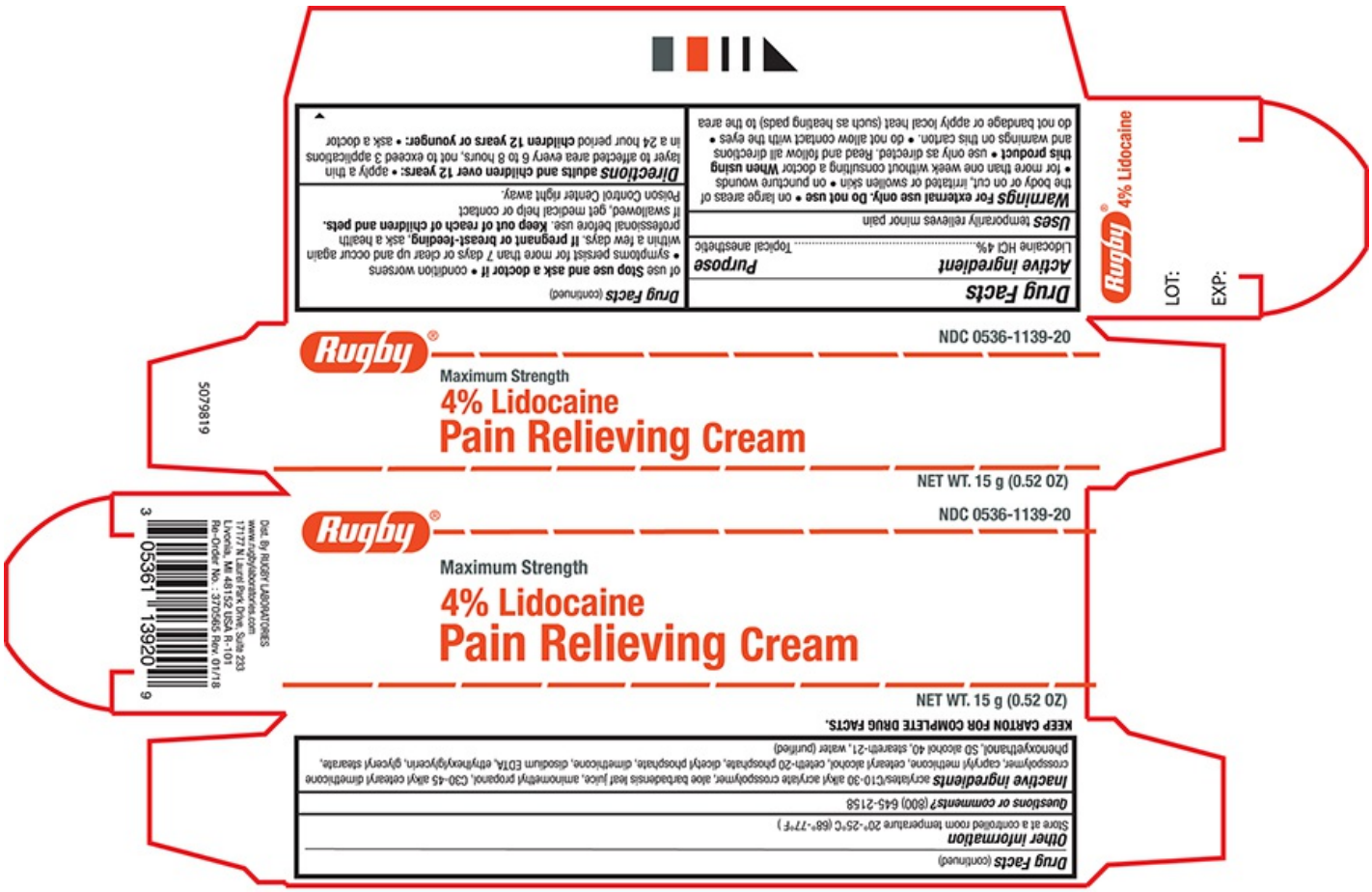
RUGBY® NDC 0536-1139-20

Maxium Strength

4% Lidocaine

Pain Relieving Cream

NET WT. 15g (0.52 oz)



RUGBY LIDOCAINE

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1139
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SILICON (UNII: Z4152N8IUI)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 132584PQMO)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

STEARETH-21 (UNII: 53J3F32P58)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETEARETH-2 PHOSPHATE (UNII: 8NSU66JGZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1139-20	1 in 1 CARTON	09/21/2018	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0536-1139-28	1 in 1 CARTON	11/27/2018	
2		30 g in 1 TUBE; 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	09/21/2018	

Labeler - Rugby Laboratories (079246066)

Revised: 1/2021 Rugby Laboratories