RUGBY LIDOCAINE- lidocaine 4% 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.

Rugby Lidocaine Cream

Lidocaine 4%

Local Anesthetic

Uses

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

For external use only.

When using this product avoid contact with eyes, do not exceed recommended dosage unless directed by a doctor, do not put this product into the rectum by using fingers or any mechanical device or applicator.

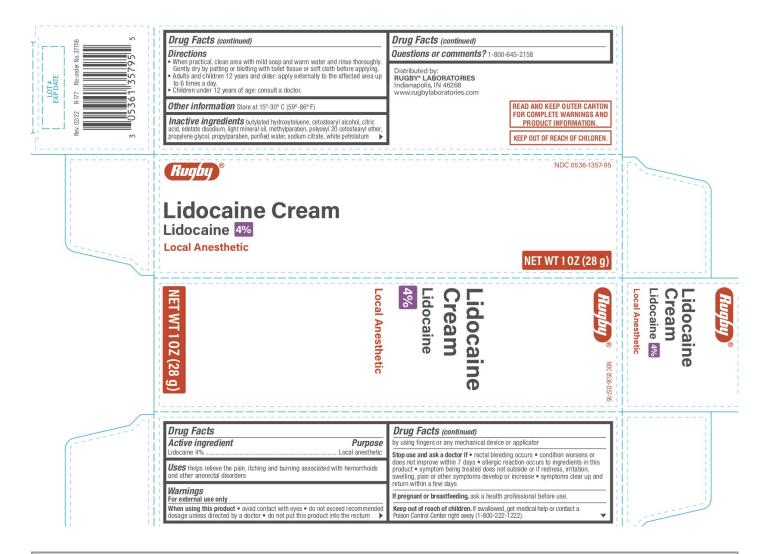
Stop use and ask a doctor if rectal bleeding occurs, condition worsens or does not improve within 7 days, allergic reaction occurs to ingredients in this product, symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, or symptoms clear up and return within a few days.

If pregnant or breastfeeding, ask a professional before use.

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

- When practical, cleanse the area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: consult a doctor.

Butylated Hydroxytoluene, Cetostearyl Alcohol, Citric Acid, Edetate Disodium, Light Mineral Oil, Methylparaben, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, White Petrolatum.



RUGBY LIDOCAINE

lidocaine 4% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1357
Route of Administration	TOPICAL		

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

Inactive Ingredients				
Ingredient Name	Strength			
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
METHYLPARABEN (UNII: A218C7H19T)				

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0536-1357- 95	1 in 1 BOX	03/02/2022			
1		28 g in 1 TUBE; Type 0: Not a Combination Product				

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Labeler - Rugby Laboratories (079246066)

Revised: 3/2022 Rugby Laboratories