

DIBUCAINE TOPICAL ANESTHETIC 1% HEMORRHOIDAL- dibucaine ointment
Rugby Laboratories Inc.

Dibucaine Topical Anesthetic 1% Hemorrhoidal Ointment

Drug Facts

Active ingredient

Dibucaine 1%

Purpose

Local Anesthetic

Use

- temporarily relieves pain and itching due to hemorrhoids and other anorectal disorders

Warnings

For external use only.

Allergy Alert

- Certain persons can develop allergic reactions to ingredients in this product. If the symptoms being treated does not subside or if redness, irritation, swelling, bleeding or other symptoms develop or increase, discontinue use and ask a doctor.

Do not use

- in or near the eyes
- in children under 2 years of age

When using this product

- do not use more than directed 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

- bleeding occurs
- condition worsens or does not improve within 7 days

If pregnant or breast-feeding

ask a health care professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center (1-800-222-1222) right away.

Directions

- adults and children 12 years and over: If possible, clean the affected area with mild soap and warm water and rinse thoroughly. Dry by patting or blotting with toilet tissue or a soft cloth before applying.
- apply externally to the affected area up to 3 to 4 times daily.
- children under 12 years of age: ask a doctor

Other information

- Store at 20 °-25 ° C (68 °-77 ° F)
- tamper-evident: do not use if foil seal is broken or missing

undefined

Lanolin, Light Mineral Oil, Purified Water, White Petrolatum

Questions or comments?

call 1-800-639-3803

Package Labeling:

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1211	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIBUCAINE (UNII: L6JW2TJG99) (DIBUCAINE - UNII:L6JW2TJG99)		DIBUCAINE	10 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
LANOLIN (UNII: 7EV65EAW6H)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
WATER (UNII: 059QF0KO0R)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1211-95	1 in 1 BOX	08/19/2019	
1		28 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 Drug	M015		08/19/2019	

Labeler - Rugby Laboratories Inc. (079246066)