

DIBUCAINE- dibucaine ointment
GERITREX LLC

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.

Dibucaine Ointment

Drug Facts

Active ingredient	Purpose
Dibucaine 1%	Topical Anesthetic

Uses

For temporary relief of pain and itching associated with sunburn, minor burns, hemorrhoids, cuts, scratches, insect bites, stings

Directions

Not for prolonged use

Adults should not use more than 1oz in 24 hours or 1/4 oz for child

Apply to affected area 3 or 4 times daily

Cover with light dressing, if necessary

Warnings

For External Use Only

Do not get into the eyes. Stop use and ask a doctor if the condition persists or if rash and irritation develops. you have rectal bleeding

Inactive Ingredients

Aceton Sodium Bisulfate, Lanolin, Mineral Oil, Purified water, White Petrolatum

KEEP OUT OF REACH OF CHILDREN

In the event of accidental ingestion, contact a Poison Control Center right away

Store at room temperature 15-30'C (59-86'F)

Apply to affected area 3 or 4 times daily



Dibucaine Ointment

1% USP

Topical Hemorrhoidal Anesthetic
NET WT. 1oz (28g)

THIS PACKAGE IS INTENDED FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN



Drug Facts

Active ingredient: Dibucaine 1%	Purpose: Local Anesthetic
Uses: Temporarily relieves pain and itching due to hemorrhoids or 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 professional before use.	
KEEP OUT OF REACH OF CHILDREN If swallowed, get medical help or contact a Poison Control Center 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. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying • apply externally to the affected area up to 3 or 4 times daily • children under 12 years of age: ask a doctor	
Other information: • Store at room temperature 20-25°C (68-77°F)	
Inactive ingredients: Acetone Sodium Bisulfate, Lanolin, Mineral Oil, Purified Water, White Petrolatum	

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DIBUCAINE

dibucaine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIBUCAINE (UNII: L6JW2TJG99) (DIBUCAINE - UNII:L6JW2TJG99)	DIBUCAINE	0.28 g in 28 g

Inactive Ingredients

Ingredient Name	Strength
ACETONE SODIUM BISULFITE (UNII: 47VY054OXY)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	

WATER (UNII: 059QF0KO0R)

PETROLATUM (UNII: 4T6H12BN9U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-011-01	28 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	07/31/2015	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-011)

Revised: 8/2017

GERITREX LLC