

CVS HEMORRHOIDAL TOPICAL ANALGESIC- dibucaine ointment

CVS Pharmacy, Inc.

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.

Active Ingredient

Purpose

Dibucaine 1%..... Local anesthetic

Use

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 20-25°C (68-77°F)

Inactive ingredients

disodium EDTA, distilled water, lanolin, mineral oil, white petrolatum

DISTRIBUTED BY:

CVS PHARMACY, INC.

ONE CVS DRIVE



CVS HEMORRHOIDAL TOPICAL ANALGESIC

dibucaine ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-997
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
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
WATER (UNII: 059QF0K00R)	
LANOLIN (UNII: 7EV65EAW6H)	

MINERAL OIL (UNII: T5L8T28FGP)

PETROLATUM (UNII: 4T6H12BN9U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-997-28	1 in 1 BOX	09/12/2016	
1		1 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 final	part346	01/17/2014	

Labeler - CVS Pharmacy, Inc. (062312574)

Revised: 9/2016

CVS Pharmacy, Inc.