

DIBUCAINE - dibucaine cream

CVS Pharmacy

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 ingredients

Purpose

Dibucaine 1%.....Hemorrhoidal/Local analgesic ointment

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Uses temporarily relieves pain and itching due to:

- hemorrhoids or other anorectal disorders - sunburn - minor burns - minor cuts
- scrapes - insect bites - minor skin irritation

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

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Other information

- to secure child resistant cap; screw cap tightly. Then turn cap in opposite direction. If clicking sound is not heard, repeat procedure.
- see crimp of tube for lot number and expiration date
- store at controlled room temperature 20 degrees to 25 degrees c (68 degrees to 77 degrees F)

Warnings

For external use only.

Allergy alert - certain persons san develop allergic reactions to ingredients in this product

Do not use

- in or near the eyes
- do not get into the eyes
- in infants under 2 years of age

- in large quantities, particularly over raw surfaces or blistered areas
- do not put this product into rectum by using fingers or any mechanical device

Stop use and ask a doctor if

- condition worsens, or does not improve within 7 days
- the symptom being treated does not subside or if redness, irritation, swelling, bleeding or other symptoms develop or increase

If pregnant or breast feeding, as a health care professional before use

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Directions

- 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

Adults and children 12 and over - apply externally to the affected area up to 3 to 4 times a day.

Children under 2 - 12 years of age - ask a doctor

Infants under 2 years of age - DO NOT USE

Inactive Ingredients

acetone sodium bisulfite, lanolin, light mineral oil, purified water, white petrolatum



DIBUCAINE

dibucaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-398
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)	
ACETONE SODIUM BISULFITE (UNII: 47VY054OXY)	

PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-398-03	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	07/16/2010		

Labeler - CVS Pharmacy (062312574)

Registrant - Pharma Pac, LLC (140807475)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Pac, LLC		140807475	manufacture

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