# DIBUCAINE- dibucaine 1% ointment Chain Drug Marketing Association 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.

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## **Quality Choice Dibucaine Ointment 1%**

### **Drug Facts**

#### **Active Ingredient**

Dibucaine 1%

Hemorrhoidal Ointment

Temporarily relieves pain and itching due to hemorrhoids or other anorectal disorders.

## If Pregnant or Breast-Feeding

Ask a health care professional before use.

## Stop Use and ask a doctor

- Bleeding occurs
- Condition worsens or does not improve within 7 days

## Keep out of the reach of Children

If swallowed, get medical help or contact a Poison Control Center right away.

#### Do Not Use

In or near eyes

In children under 2 years of age

## **Warnings**

For External use only

Allergy alert

Certain persons can develop allergic reactions to ingredients in this product.

If the symptoms being treated do not subside or if redness, irritation, swelling, bleeding or other symptoms develop or increase, discontinue use and ask a doctor.

## 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.

#### **Directions**

- Adults and children 12 years of age or older. If possible, clean the affected area by
  patting or blotting with appropriate cleansing wipes or with mild soap and warm water
  and rinse thoroughly. Gently dry by patting or blotting with a 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

#### **Questions or Comments?**

Call Toll Free 1-800-935-2362

#### Other Information

• Store at room temperature 20°-25°C (68°-77°F)

## Inactive Ingredients

Lanolin, Light Mineral Oil, Purified Water, White Petrolatum

## **Distributed By**

Distributed by: CDMA, Inc.

Novi, MI 48375 USA

1-800-935-2362

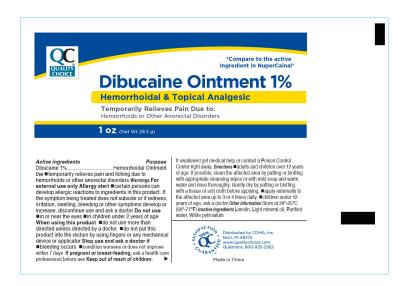
\* This product is not manufactured or distributed by Ducere Pharma, Distributor of Nuper-Cainal

## **Packaging**

#### **OUTSIDE BOX**



#### **INNER TUBE**



#### **DIBUCAINE**

dibucaine 1% ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-911	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIBUCAINE (UNII: L6JW2TJG99) (DIBUCAINE - UNII:L6JW2TJG99)	DIBUCAINE	1 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)		
WATER (UNII: 059QF0KO0R)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
LANOLIN (UNII: 7EV65EAW6H)		

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63868-911- 01	1 in 1 BOX	09/14/2022		
1	L	28.3 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	09/14/2022		

## Labeler - Chain Drug Marketing Association Inc. (011920774)

**Registrant -** Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 5/2023 Chain Drug Marketing Association Inc.