

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.

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

<p>Drug Facts</p> <p>Active Ingredients Dibucaine 1%..... Hemorrhoidal Ointment</p> <p>Purpose Hemorrhoidal Ointment</p> <p>Use temporarily relieves pain and itching due to hemorrhoids or other anorectal disorders</p> <p>Warnings For external use only Allergy alert certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation,</p>		<p>Drug Facts (continued)</p> <p>swelling, bleeding or other symptoms develop or increase, discontinue use and ask a doctor.</p> <p>Do not use in or near the eyes in children under 2 years of age</p> <p>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</p>	
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NDC: 63868-911-01

Dibucaine Ointment 1%

Dibucaine Ointment 1%

Hemorrhoidal & Topical Analgesic


Temporarily Relieves Pain Due to: Hemorrhoids or Other Anorectal Disorders

1 oz (Net Wt 28.3 g)


*Compare to the active ingredient in NuperCainal®

<p>Drug Facts (continued)</p> <p>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 right away.</p> <p>Directions adults and children over 12 years of age: If possible, clean the affected area by</p>		<p>Drug Facts (continued)</p> <p>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 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</p> <p>Other Information Store at room temperature 20°-25°C (68°-77°F)</p> <p>Inactive Ingredients Lanolin, Light mineral oil, Purified water, White petrolatum</p>	
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Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362




6 35515 99887 2

LOT:
EXP:

Made in China

INNER TUBE

Dibucaine Ointment 1%



Dibucaine Ointment 1%

Hemorrhoidal & Topical Analgesic


Temporarily Relieves Pain Due to:
Hemorrhoids or Other Anorectal Disorders

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<p>Active ingredients Dibucaine 1%..... Hemorrhoidal Ointment</p> <p>Purpose Hemorrhoidal Ointment</p> <p>Use temporarily relieves pain and itching due to hemorrhoids or other anorectal disorders</p> <p>Warnings For external use only Allergy alert certain persons can develop allergic reactions to ingredients in this product. If the symptom 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</p> <p>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.</p>	<p>If swallowed get medical help or contact a Poison Control Center right away. Directions adults and children over 12 years of age: 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 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 Lanolin, Light mineral oil, Purified water, White petrolatum</p>
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LOT:
EXP:

Made in China

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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-911-01	1 in 1 BOX	09/14/2022	
1		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)