DIBUCAINE- dibucaine 1% ointment Trifecta Pharmaceuticals USA LLC

Globe 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 platting or blotting with an appropriate cleansing wipe, 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 1-888-296-9067

Other Information

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

Inactive Ingredients

Lanolin, Light Mineral Oil, Purified Water, White Petrolatum

Distributed By

Trifecta Pharmaceuticals USA

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

1-888-296-9067

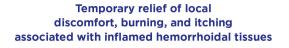
Made in China

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

Child Resistant Packaging

Packaging

OUTSIDE BOX





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COMPARE TO the active ingredients of NUPER-CAINAL*



Burning & Itching Associated with Inflamed Hemorrhoidal Tissues

NDC: 69396-023-01

Temporary Relief of Local Discomfort,

NET WT. 1 OZ. (28.4G)

Other Information
Store at room temperature 20°-25°C (68°-77°F)
Inactive Ingredients
Lanolin, Light mineral oil, Purified water, White petrolatum

Drug Facts (continued)

Questions or Comments?

Drug Facts Active ingredient Dibucaine 1% Purpose .. Hemorrhoidal Ointment Use temporarily relieves pain and itching due to hemorrhoids or other anorectal disorders Warnings For external use only

Drity Facts (communes)

Directions

a duths and children over 12 years of age: If possible, clean the affected area by patting or blotting with an appropriate cleansing wice, early 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

Drug Facts (continued)

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■ in children under 2 years of age
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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 doctor before use
Keep out of reach of children. I snatowed get medical help or contact a Poson Control Center right away
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Allergy alert © critain 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

Distributed by: 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA

Child Resistant Packaging Distributed by:

Trifecta Pharmaceuticals USA*

101 NE Third Avenue, Suite 1500

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DIBUCAINE HEMORRHOID & TOPICAL ANALGESIC

INNER TUBE



DIBUCAINE

dibucaine 1% ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69396-023

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TOPICAL

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

Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			
WATER (UNII: 059QF0KO0R)			
LIGHT MINERAL OIL (UNII: N6K5787OVP)			

LANOLIN (UNII: 7EV65EAW6H)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69396-023- 01	1 in 1 BOX	09/14/2022		
1		28.4 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 Drug	M017	09/14/2022		

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Registrant - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 1/2024 Trifecta Pharmaceuticals USA LLC