

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 patting 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

Temporary relief of local discomfort, burning, and itching associated with inflamed hemorrhoidal tissues



EXP. LOT

COMPARE TO the active ingredients of NUPER-CAINAL*




DIBUCAINE


HEMORRHOID & TOPICAL ANALGESIC

NET WT. 1 OZ. (28.4G)

NDC: 69396-023-01

Temporary Relief of Local Discomfort, Burning & Itching Associated with Inflamed Hemorrhoidal Tissues

<p>Drug Facts</p> <p>Active ingredient Dibucaine 1% 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 symptoms being treated do not subside or if redness, irritation, swelling, bleeding or other symptoms develop or increase, discontinue use and ask a doctor</p>	<p>Drug Facts (continued)</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> <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 doctor 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 patting or blotting with an appropriate cleansing wipe, 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> <p>Questions or Comments? Call Toll Free 1-888-296-9067</p>	<p>Distributed by: Trifecta Pharmaceuticals USA* 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA www.trifecta-pharma.com</p> <p>Child Resistant Packaging *This product is not manufactured or distributed by Ducera Pharma, distributor of Nuper-Cainal*</p>  <p>8 50026 39341 5 Made in China</p>




DIBUCAINE
HEMORRHOID & TOPICAL ANALGESIC

INNER TUBE

COMPARE TO the active ingredients of NUPER-CAINAL*

NDC: 69396-023-01



DIBUCAINE

HEMORRHOID & TOPICAL ANALGESIC

NET WT. 1 OZ. (28.4G)

<p>Active ingredient Dibucaine 1% Purpose Hemorrhoidal ointment</p> <p>Uses : Temporary 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 do not subside or if redness, irritation, swelling, pain 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 in 7 days</p>	<p>If pregnant or breast-feeding, ask a doctor before use Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>Directions : • adults and children over 12 years of age: If possible, clean the affected area by patting or blotting with an appropriate cleansing wipe, 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 controlled room temperature 20°-25° C (68°-77° F) Inactive Ingredients Lanolin, Light mineral oil, Purified water, White petrolatum</p> <p>Questions? Call 1-888-296-9067</p>
<p>Distributed by: Trifecta Pharmaceuticals USA* 101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA Made in China www.trifecta-pharma.com</p>	

DIBUCAINE
dibucaine 1% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-023
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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
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
LANOLIN (UNII: 7EV65EAW6H)	

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