DIBUCAINE- dibucaine ointment
Akron Pharma 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.

Dibucaine Ointment

Drug Facts

Active ingredient	Purpose
Dibucaine 1%	Topical Anesthetic

Uses

For temporary relief of pain and itching associated with sunburn, minor burns, hemorrhoids, cuts, scratches, insect bites, stings

Directions

Not for prolonged use

Adults should not use more than 1oz in 24 hours or 1/4 oz for child

Apply to affected area 3 or 4 times daily

Cover with light dressing, if necessary

Warninigs

For External Use Only

Do not get into the eyes. Stop use and ask a doctor if the condition persists of if rash and irritation develops. you have rectal bleeding

Inactive Ingredients

Sodium Metabisulfite, Lanolin,White Petrolatum

KEEP OUT OF REACH OF CHILDREN

In the event of accidental ingestion, contact a Poison Control Center right away

Store at room temperature 15-30'C (59-86'F)

Apply to affected area 3 or 4 times daily

Questions or Comments?

Call (877) 225-6999 Monday - Friday 9AM-5PM EST

Manufactured for
Akron Pharma, Inc.,
Fairfeld, NJ - 07004

Manufactured In USA

Akron Pharma

NDC 71399-2829-1

DIBUCAINE 1%

HEMORRHOIDAL OINTMENT

- *Fast Temporary Relief of Local Discomfort, Pain, Itching and Burning Due to Hemorrhoids*
- *Provides Numbing Relief*

Child Resistant Packaging

*Compare to Nupercainal®
active ingredient

Net Wt. 1oz (28g)
Made in USA

Drug Facts

Active ingredient ***Purpose***
Dibucaine 1%..... Hemorrhoidal ointment

Use ■ temporarily 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 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 children under 2 years of age ■ in or near the eyes

When using this product ■ avoid contact with eyes ■ 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

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.

Drug Facts *(continued)*

Stop use and ask a doctor if ■ bleeding occurs ■ condition worsens or does not improve within 7 days

Directions ■ adults and children 12 years and over: if possible, clean the affected area with mild soap and warm water and rinse thoroughly. Dry by patting or blotting with toilet tissue or a 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 room temperature 20°-25°C (68°-77°F)

Inactive ingredients lanolin, sodium metabisulfite, white petrolatum.

Questions or comments? call toll-free 1(877)225-6999.

*This product is not manufactured or distributed by the owner of the registered trademark Nupercainal®

Akron Pharma
Manufactured for:
Akron Pharma Inc,
Fairfield, NJ-07004
www.akronpharma.com
Rev.:12/20

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Akron Pharma

NDC 71399-2829-2

DIBUCAINE 1%

HEMORRHOIDAL OINTMENT

- *Fast Temporary Relief of Local Discomfort, Pain, Itching and Burning Due to Hemorrhoids*
- *Provides Numbing Relief*

Child Resistant Packaging

*Compare to Nupercainal® active ingredient

Net Wt. 2oz (56g)

Made in USA

Drug Facts

Active ingredient ***Purpose***
Dibucaine 1%..... Hemorrhoidal ointment

Use ■ temporarily 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 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 children under 2 years of age ■ in or near the eyes

When using this product ■ avoid contact with eyes ■ 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 ▶

Drug Facts *(continued)*

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

Stop use and ask a doctor if ■ bleeding occurs ■ condition worsens or does not improve within 7 days

Directions ■ adults and children 12 years and over: if possible, clean the affected area with mild soap and warm water and rinse thoroughly. Dry by patting or blotting with toilet tissue or a 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

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www.akronpharma.com

Rev.:12/20

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DIBUCAINE

dibucaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-2829
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIBUCAINE (UNII: L6JW2TJG99) (DIBUCAINE - UNII:L6JW2TJG99)	DIBUCAINE	0.28 g in 28 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-2829-1	28 g in 1 TUBE; Type 0: Not a Combination Product	11/04/2021	
2	NDC:71399-2829-2	1 in 1 PACKAGE	11/04/2021	
2		56 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	11/04/2021	

Labeler - Akron Pharma Inc. (067878881)

Registrant - SLV PHARMACEUTICALS LLC (081225162)

Establishment

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC		081225162	manufacture(71399-2829)

Revised: 2/2023 Akron Pharma Inc.