DIBUCAINE- dibucaine ointment
E. Fougera & Co. a division of Fougera Pharmaceuticals 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 USP, 1%

Active Ingredient:

Dibucaine 1%

Purpose:

Topical Anesthetic

Uses:

- for temporary relief of pain and itching associated with:
- sunburn
- minor burns
- hemorrhoids
- cuts
- scratches
- insect bites
- stings

Warnings:

For external use only

Do not use in the eyes

Stop use and ask a doctor if

- the condition persists or if rash or irritation develops
- you have rectal bleeding

Keep out of reach of children.

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

Directions:

- not for prolonged use
- adults should not use more than the tube in 24 hours or 1/4 tube for child
- apply to affected area 3 or 4 times daily
- cover with light dressing, if necessary

Other information:

- store at room temperature.
- see crimp of tube for Lot Number and Expiration Date.

Inactive Ingredients

acetone sodium bisulfite 1/2% as a preservative, lanolin, purified water, white petrolatum

Questions or comments? call toll free 1-800-645-9833

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.

Melville, NY 11747

C4905B

R12/11

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera®

NDC 0168-0046-31

CHILD-RESISTANT PACKAGE

DIBUCAINE OINTMENT USP, 1%

TOPICAL ANESTHETIC

NET WT 28.35g (1 Oz)

FOR EXTERNAL USE ONLY

DO NOT USE IN THE EYES

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

NDC 0168-0046-31

Fougera®

DIBUCAINE OINTMENT USP, 1%

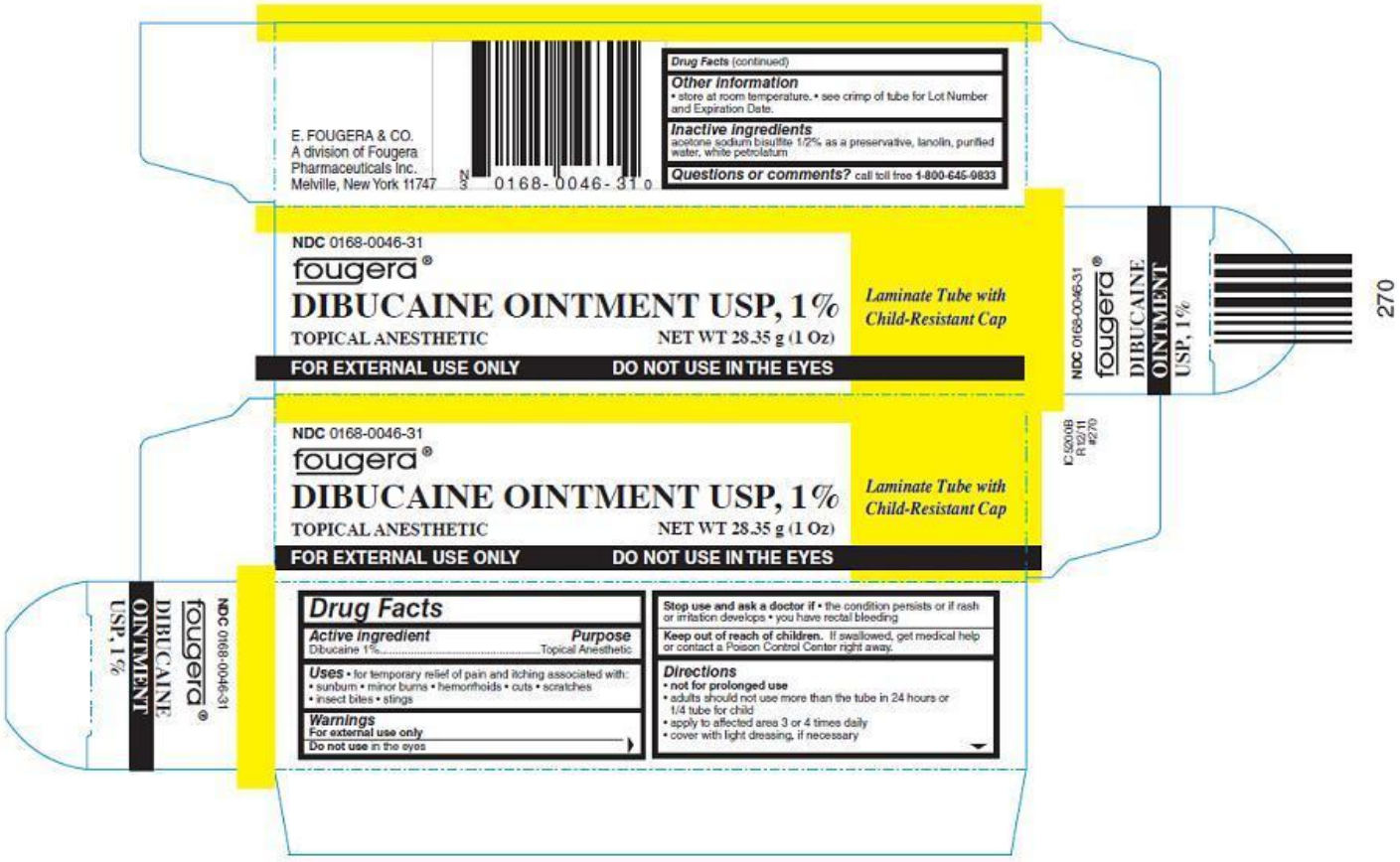
TOPICAL ANESTHETIC

NET WT 28.35g (1 Oz)

Laminate Tube with Child-Resistant Cap

FOR EXTERNAL USE ONLY

DO NOT USE IN THE EYES



DIBUCAINE

dibucaine ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0168-0046
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**
ACETONE SODIUM BISULFITE (UNII: 47VY054OXY)	

LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0046-31	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/01/1968	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

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