

VITAMIN A AND VITAMIN D- vitamin a and vitamin d 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.

Vitamin A & Vitamin D Ointment

Active Ingredient:

White Petrolatum (929.3 mg)

Purpose:

Emollient

Uses:

- first aid in
- minor burns
- scalds
- sunburn
- windburn
- diaper rash
- chafing
- chapped skin
- nipple care
- abrasions
- cuts
- ulcers

Warnings:

For external use only.

Ask doctor before use if you have severe or extensive burns.

When using this product the treatment of ulcers, severe cuts or wounds should be under the direction of a doctor.

Keep out of reach of children.

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

Directions:

- cleanse affected area with mild soap and warm water
- dry thoroughly
- apply Vitamin A & Vitamin D ointment in a thin layer to the affected area directly to the skin or by spreading on sterile gauze or clean cloth
- bandage loosely

Other information:

- do not use if seal is punctured or is not visible. To open, reverse cap to puncture seal
- store at room temperature
- see crimp of tube for Lot Number and Exp. Date

Inactive Ingredients

fragrance, lanolin, paraffin, vitamin A (as palmitate), vitamin D

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

E. FOUGERA & CO.

A division of Fougera Pharmaceuticals Inc.

Melville, NY 11747

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

NDC 0168-0035-01

Fougera®

Vitamin A & Vitamin D Ointment

(Emollient)

NET WT 56.70 g (2 Oz)

FOR EXTERNAL USE ONLY

DO NOT USE IN THE EYES

NDC 0168-0035-01

NET WT 56.70 g (2 Oz)

fougera[®]

Vitamin A & Vitamin D Ointment (Emollient)

FOR EXTERNAL USE ONLY

DO NOT USE IN THE EYES

Drug Facts	
Active ingredient (in each gram) White Petrolatum (929.3 mg).....	Purpose Emollient
Uses first aid in • minor burns • scalds • sunburn • windburn • diaper rash • chafing • chapped skin • nipple care • abrasions • cuts • ulcers	
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E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747

X5110C
R02/12



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

Fougera[®]

NDC 0168-0035-01

Vitamin A & Vitamin D Ointment (Emollient)

To promote healing of minor skin irritations

NET WT 2 Oz (56.70 g)



Drug Facts (continued)

Inactive ingredients fragrance, lanolin, paraffin, vitamin A (as palmitate), vitamin D

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

E. FOUGERA & CO
A division of Fougera Pharmaceuticals Inc., Melville New York 11747

IX5110F
R02/12
#65



NDC 0168-0035-01

Vitamin A & Vitamin D Ointment (Emollient)

To promote healing of minor skin irritations

NET WT 2 Oz (56.70 g)



65

Drug Facts	
Active ingredient (in each gram)	Purpose
White Petrolatum (929.3 mg).....	Emollient
Uses first aid in • minor burns • scalds • sunburn • windburn • diaper rash • chafing • chapped skin • nipple care • abrasions • cuts • ulcers	
Warnings For external use only.	
Ask doctor before use if you have severe or extensive burns.	

Drug Facts (continued)	
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PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera®

NDC 0168-0035-45

Vitamin A & Vitamin D Ointment

(Emollient)

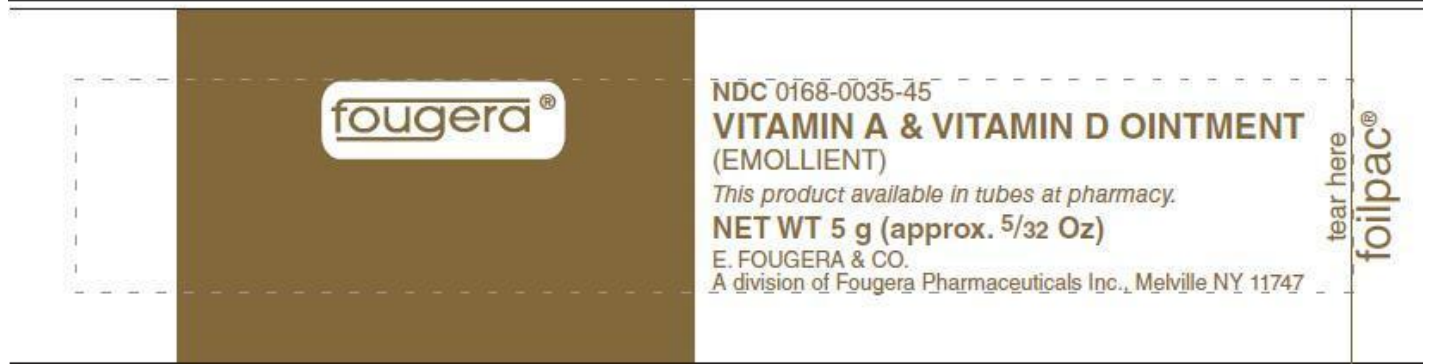
This product available in tubes at pharmacy

NET WT 5 g (approx. 5/32 Oz)

E. FOUGERA & CO.

A division of Fougera Pharamceuticals Inc., Melville, NY 11747

Active ingredient (in each gram) White Petrolatum (929.3 mg) **Purpose** Emollient **Uses** for first aid in • minor burns • scalds • sunburn • windburn • diaper rash • chafing • chapped skin • nipple care • abrasions • cuts • ulcers **Warnings** For external use only. Ask doctor before use if you have severe or extensive burns. When using this product the treatment of ulcers, severe cuts or wounds should be under the direction of a doctor. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. **Directions** • cleanse affected area with mild soap and warm water • dry thoroughly • apply Vitamin A & Vitamin D ointment in a thin layer to the affected area directly to the skin or by spreading on sterile gauze or a clean cloth • bandage loosely **Other information** • store at room temperature **Inactive ingredients** fragrance, lanolin, paraffin, vitamin A (as palmitate), vitamin D **Questions or comments?** call toll free 1-800-645-9833 FP5013C_R02/12



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

NDC 0168-0035-45

Fougera®

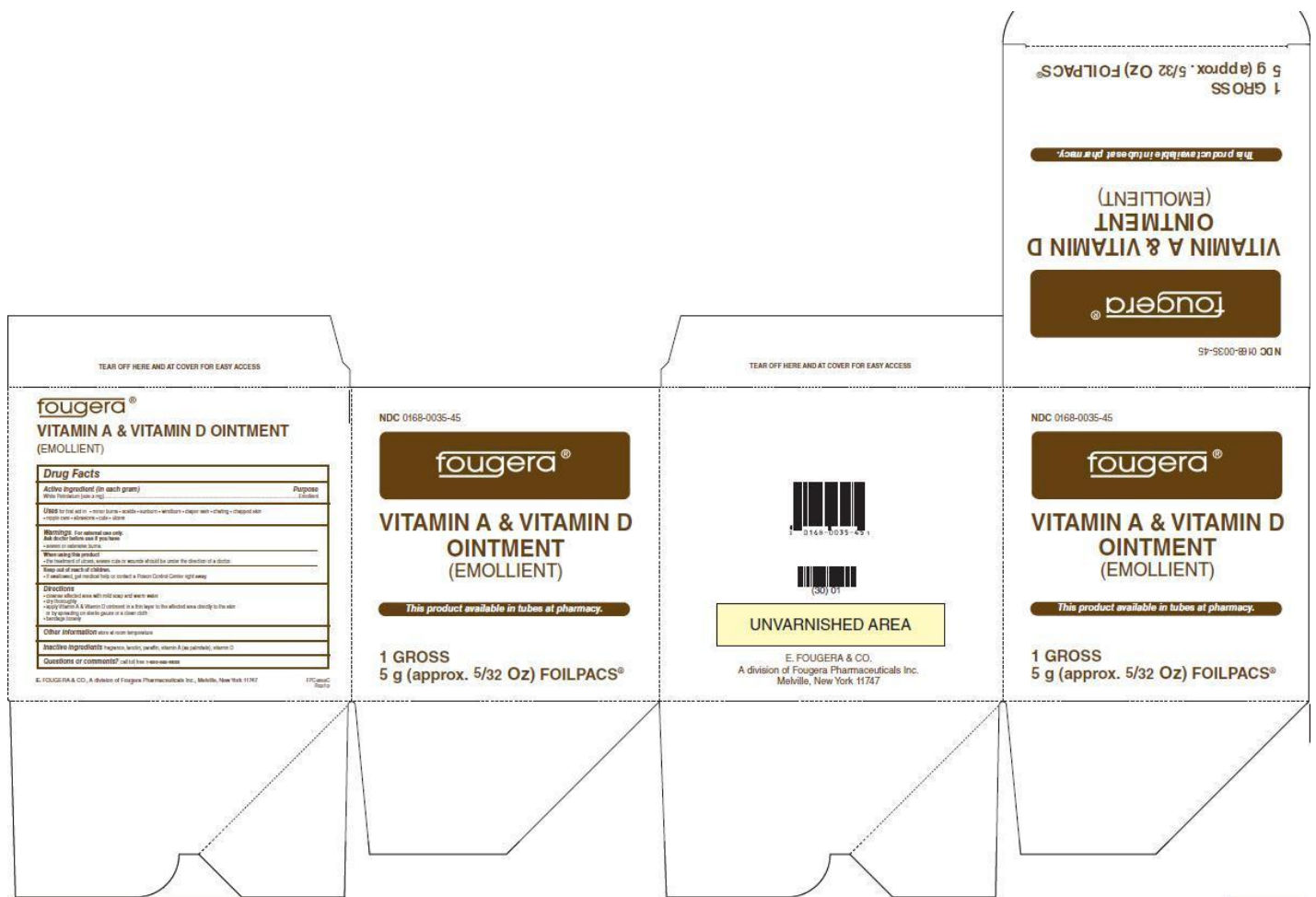
**Vitamin A & Vitamin D
Ointment**

(Emollient)

This product available in tubes at pharmacy

1 GROSS

5 g (approx. 5/32 Oz) FOILPACS®





PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera®

NDC 0168-0035-16

**Vitamin A & Vitamin D
Ointment (Emollient)**

NET WT 453.6 g (1 lb)

	<p>NDC 0168-0035-16 Vitamin A & Vitamin D Ointment (Emollient) NET WT. 453.6 g (1lb)</p>																															
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VITAMIN A AND VITAMIN D

vitamin a and vitamin d ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	929.3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
PARAFFIN (UNII: I9O0E3H2ZE)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
VITAMIN D (UNII: 9VU1K144GP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0035-01	1 in 1 CARTON		
1		56.70 g in 1 TUBE		
2	NDC:0168-0035-02	72 in 1 CARTON		
2		56.70 g in 1 TUBE		
3	NDC:0168-0035-04	1 in 1 CARTON		
3		113.4 g in 1 TUBE		
4	NDC:0168-0035-45	1 in 1 CARTON		
4		5 g in 1 PACKET		
5	NDC:0168-0035-16	453.6 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/1981	

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

Revised: 9/2012

E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.