#### ZINC OXIDE- zinc oxide 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.

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#### ZINC OXIDE

#### Active Ingredient:

Zinc Oxide (200 mg)

#### Purpose:

Skin protectant

#### Uses:

- helps treat and prevent diaper rash
- dries the oozing and weeping of:
- poison ivy
- poison oak
- poison sumac

#### Warnings:

If condition worsens or dose not improve within seven days, consult physician.

# Keep out of reach of children.

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

# FOR EXTERNAL USE ONLY

# AVOID CONTACT WITH EYES

#### **Directions:**

- For diaper rash:
- change wet and soiled diapers promptly, allow to dry
- apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged. To dry the oozing and weeping of poison ivy, poison oak or poison sumac:
- apply ointment liberally as often as needed

#### Other information:

- do not use if seal is punctured or is not visible
- use cap to puncture seal
- store at temperature
- do not exceed 30° C (86° F)

#### **Inactive Ingredients**

mineral oil, white petrolatum, white wax

#### 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 0168-0062-31

Fougera<sup>®</sup>

Zinc Oxide Ointment USP

NET WT 28.35g (1 Oz)

NDC 0168-0062-31

# Oxide Ointment USP

#### **Drug Facts**

Active ingredient (in each gram) Purpose Zinc oxide (200 mg)..... .....Skin protectant Use(s) . helps treat and prevent diaper rash . dries the oozing and weeping of: . poison ivy poison oak • poison sumac Warnings If condition worsens or does not improve within seven days, consult physician. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. AVOID CONTACT WITH EYES FOR EXTERNAL USE ONLY Directions For diaper rash: • change wet and soiled diapers promptly, allow to dry • apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged. To dry the oozing and weeping of poison ivy, poison oak or poison sumac: apply ointment liberally as often as needed Other information • do not use if seal is punctured or is not visible • use cap to puncture seal R12/11

NET WT 28.35 q (1 Oz)

 store at room temperature • do not exceed 30°C (86°F) Inactive ingredients mineral oil, white petrolatum, white wax Questions or comments? call toll free 1-800-645-9833

E. FOUGERA & CO., A division of Fougera Pharmaceuticals Inc., Melville, New York 11747 W5165B



# PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

NDC 0168-0062-31

Fougera<sup>®</sup>

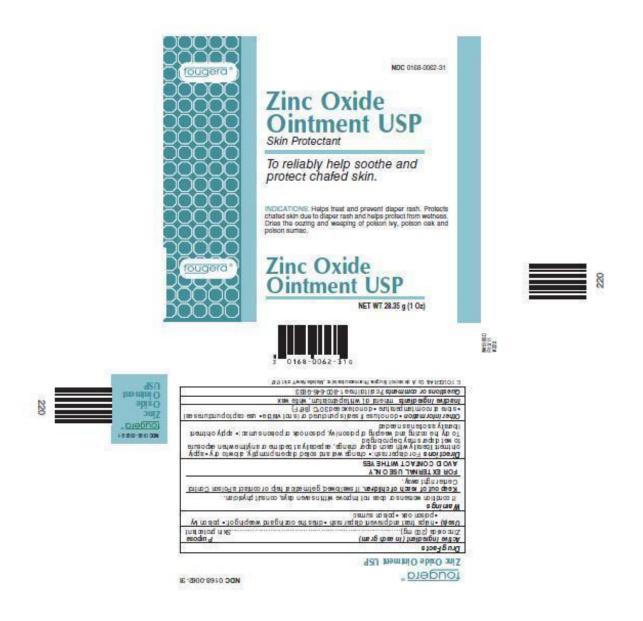
#### Zinc Oxide Ointment USP

Skin Protectant

To reliably help soothe and protect chafed skin.

INDICATION: Helps and prevent diaper rash. Protects chafed skin due to diaper rash and helps protect from wetness. Dries the oozing and weeping of poison ivy, poison oak and poison sumac.

NET WT 28.35g (1 Oz)



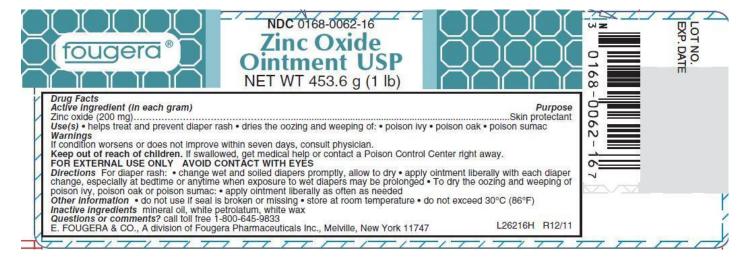
# PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera<sup>®</sup>

NDC 0168-0062-16

#### Zinc Oxide Ointment USP

NET WT 453.6 g (1 lb)



ZINC OXIDE									
zinc oxide ointment									
Product Information									
Product Type		HUMAN OTC DRUG	HUMAN OTC DRUG Item (		ode (Source)		NDC:0168-0062		
Route of Administration		on TOPICAL							
Active Ingredient/Active Moiety									
		Ingredient Name	redient Name		Basis of Streng		gth	Strength	
Z	INC OXIDE (UNII: SOI2	LOH54Z) (ZINC OXIDE - UNII:SOI2LOF	C OXIDE - UNII:SOI2LOH54Z)			2	200 mg in 1 g		
Inactive Ingredients									
Ingredient Name							Strength		
MINERAL OIL (UNII: T5L8T28FGP)									
PETROLATUM (UNII: 4T6H12BN9U)									
WHITE WAX (UNII: 7G1J5DA97F)									
Packaging									
#	Item Code	Package Description	Marketii	arketing Start Date		Marketing End Date			
	NDC:0168-0062-31	1 in 1 CARTON							
1		28.35 g in 1 TUBE							
	NDC:0168-0062-02	1 in 1 CARTON							
2	NDC-0169 0062 16	56.70 g in 1 TUBE							
3	NDC:0168-0062-16	453.6 g in 1 JAR							
Marketing Information									
N	Iarketing Category	Application Number or Monogra	ation Number or Monograph Citation		Marketing Start Date		Marketing End Date		
0	TC monograph final	part347		0 1/0 1/	1968				

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

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