

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.

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 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.

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®

Zinc Oxide Ointment USP

NET WT 28.35g (1 Oz)

NDC 0168-0062-31

fougera®

Zinc Oxide Ointment USP

NET WT 28.35 g (1 Oz)

Drug Facts

Active ingredient (in each gram)

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.

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 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

Purpose

W5165B
R12/11



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

NDC 0168-0062-31

Fougera®

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)

NDC 0168-0062-16

Zinc Oxide Ointment USP
NET WT 453.6 g (1 lb)

LOT NO.
EXP. DATE

3
N
0168-0062-167

Drug Facts
Active ingredient (in each gram)
 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
Purpose
 Skin protectant
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.
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 broken or missing • 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 L26216H R12/11

ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0062
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	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	Marketing Start Date	Marketing End Date
1	NDC:0168-0062-31	1 in 1 CARTON		
1		28.35 g in 1 TUBE		
2	NDC:0168-0062-02	1 in 1 CARTON		
2		56.70 g in 1 TUBE		
3	NDC:0168-0062-16	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	01/01/1968	

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

Revised: 9/2012

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