

WHITE PETROLATUM- white petrolatum 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.

White Petrolatum USP

Active Ingredient:

White Petrolatum USP 100%

Purpose:

Skin Protectant

Uses:

- temporary protection of minor
- cuts
- scrapes
- burns
- sunburn
- chafed or chapped skin
- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps protect from wetness

Warnings:

For external use only

When using this product

- avoid contact with eyes
- not to be applied over deep or puncture wounds, infections or lacerations

Stop use and ask a doctor if

- the condition persists or gets worse
- if a rash or other allergic reaction develops

Keep out of reach of children.

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

Directions:

- change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information:

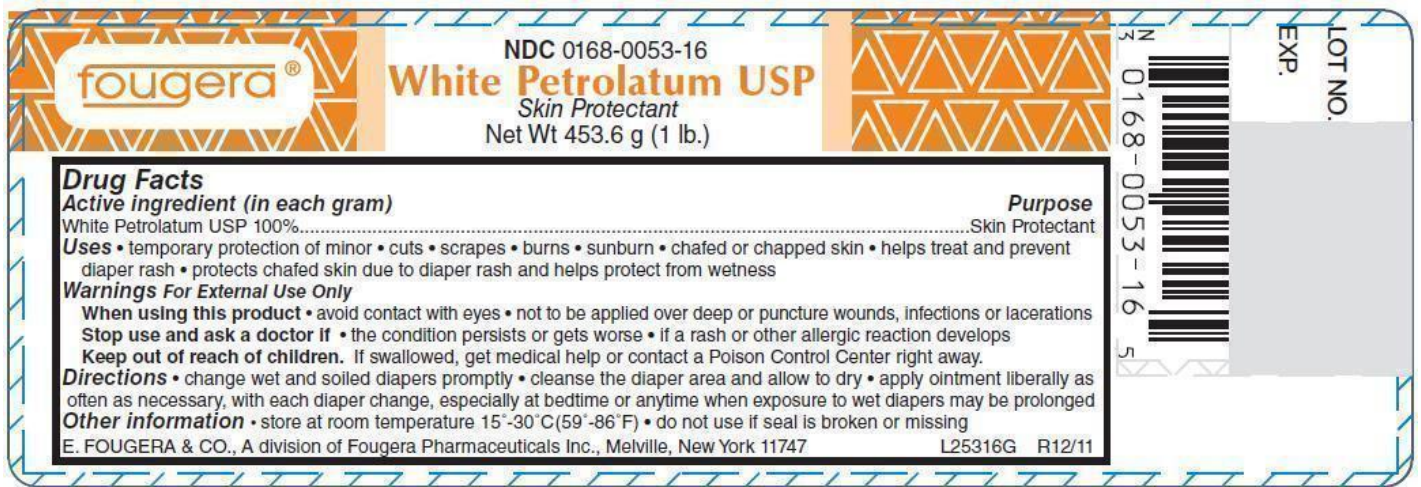
- store at room temperature 15°-30°C (59°-86°F)

- do not sure if seal is broken or missing

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

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera®
 NDC 0168-0053-16
White Petrolatum USP
Skin Protectant
 NET WT 453.6g (1 lb.)



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

Fougera®
 NDC 0168-0053-21
White Petrolatum USP
Skin Protectant
 NET WT 28.35g (1 Oz)

fougera®

NDC 0168-0053-21

White Petrolatum USP

Skin Protectant

NET WT 28.35 g (1 Oz)

Active ingredient (in each gram)

White Petrolatum USP.....

Purpose

.....Skin Protectant

Uses • temporary protection of minor • cuts • scrapes • burns • sunburn • chafed or chapped skin • helps treat and prevent diaper rash • protects chafed skin due to diaper rash and helps protect from wetness

Warnings For external use only

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Directions • change wet and soiled diapers promptly • cleanse the diaper area and allow to dry • apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information • do not use if seal is punctured or is not visible. To open, reverse cap to puncture seal • store at room temperature 15°-30°C (59°-86°F) • see crimp of tube for Lot No. and Exp. Date

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

E. FOUGERA & CO.,

A division of Fougera Pharmaceuticals Inc.

Melville, New York 11747

W5112C R12/11



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

Fougera®

NDC 0168-0053-21

White Petrolatum USP

Skin Protectant

Soothes minor skin irritations due to:
minor burns - scrapes - abrasions

fougera®

NDC 0168-0053-21

White Petrolatum USP

Skin Protectant

Soothes minor skin irritations due to:
• minor burns • scrapes • abrasions

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

fougera®

White Petrolatum USP

Skin Protectant

NET WT 28.35 g (1 Oz)



IWS 112C
R12/11
#213

NDC 0168-0053-21
fougera®
White Petrolatum USP

Drug Facts
Active ingredient (in each gram) White Petrolatum USP.....Skin Protectant
Uses • temporary protection of minor cuts • scrapes • burns • sunburn • chafed or chapped skin • helps treat and prevent diaper rash • protects chafed skin due to diaper rash and helps protect from wetness
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NDC 0168-0053-21

fougera®
White Petrolatum USP

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CONTAINER

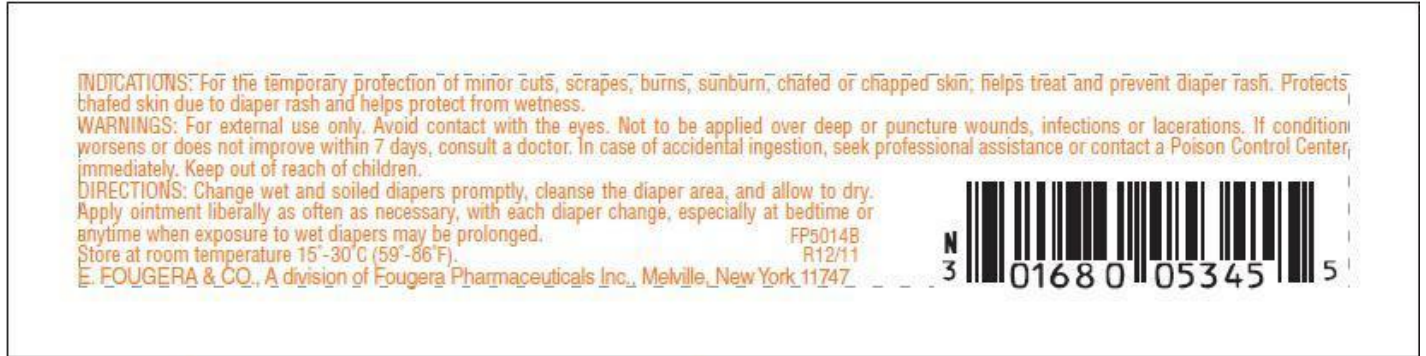
Fougera®

NDC 0168-0053-45

White Petrolatum USP

Skin Protectant

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



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – CARTON

Fougera®

NDC 0168-0053-45

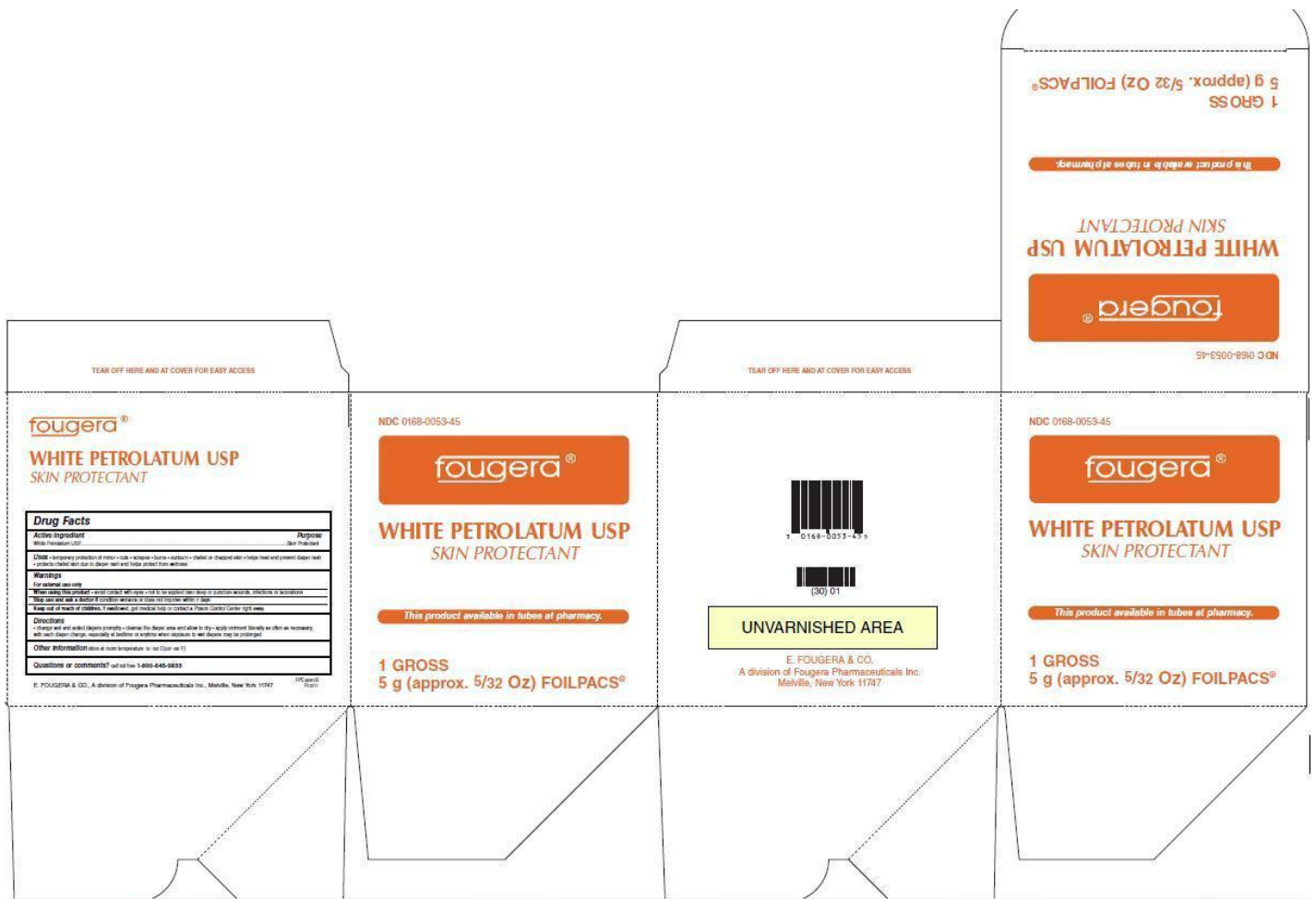
White Petrolatum USP

Skin Protectant

This product is available as tubes at pharmacy.

1 GROSS

5g (approx. 5/32 Oz) FOILPACS®



WHITE PETROLATUM

white petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0168-0053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0053-16	453.6 g in 1 JAR		

2	NDC:0168-0053-21	1 in 1 CARTON		
2		28.35 g in 1 TUBE		
3	NDC:0168-0053-31	144 in 1 CARTON		
3		28.35 g in 1 TUBE		
4	NDC:0168-0053-45	1 in 1 CARTON		
4		5 g in 1 PACKET		

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: 8/2012

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