BETAMETHASONE DIPROPIONATE- betamethasone dipropionate cream
BETAMETHASONE DIPROPIONATE- betamethasone dipropionate ointment
BETAMETHASONE DIPROPIONATE- betamethasone dipropionate lotion
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

BETAMETHASONE DIPROPIONATE CREAM USP, 0.05%
BETAMETHASONE DIPROPIONATE OINTMENT USP, 0.05%
BETAMETHASONE DIPROPIONATE LOTION USP, 0.05%

(Potency expressed as betamethasone)

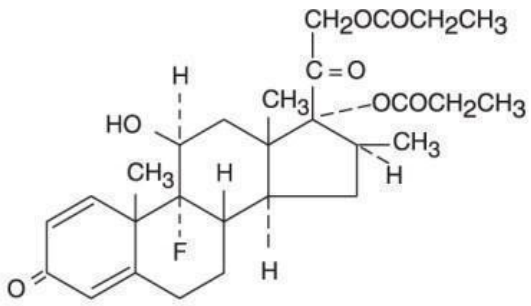
Rx only

FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Betamethasone Dipropionate Cream, Ointment and Lotion contain betamethasone dipropionate USP, a synthetic adrenocorticosteroid, for dermatologic use. Betamethasone, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Betamethasone dipropionate is a white to cream white odorless crystalline powder insoluble in water. Chemically, it is 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate. The structural formula is:



Molecular Formula: $C_{28}H_{37}FO_7$ Molecular Weight: 504.60

Each gram of the 0.05% Cream contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in a soft, white, hydrophilic cream of purified water, mineral oil, white petrolatum, polyoxyl 20 cetostearyl ether, cetostearyl alcohol, monobasic sodium phosphate (monohydrate); chlorocresol is present as a preservative. Sodium hydroxide or phosphoric acid solution to adjust pH, if required.

Each gram of the 0.05% Ointment contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in an ointment base of mineral oil and white petrolatum.

Each gram of the 0.05% Lotion contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in a vehicle of isopropyl alcohol and purified water

slightly thickened with carbomer 934P. Sodium hydroxide solution to adjust pH, if required.

CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids (See **DOSAGE AND ADMINISTRATION**).

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings (See **DOSAGE AND ADMINISTRATION**).

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by

using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (See **PRECAUTIONS—Pediatric Use**). If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive.
4. Patients should report any signs of local adverse reactions.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings (See **DOSAGE AND ADMINISTRATION**).

Laboratory tests: The following tests may be helpful in evaluating HPA axis suppression:

Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities **not** likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently when Betamethasone Dipropionate products are used as recommended in the **DOSAGE AND ADMINISTRATION** section. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infections, skin atrophy, striae and miliaria.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria in some patients.

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (See **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION:

Apply a thin film of Betamethasone Dipropionate Cream or Ointment to the affected skin areas once daily. In some cases, twice daily dosage may be necessary.

Apply a few drops of Betamethasone Dipropionate Lotion to the affected skin areas and massage lightly until it disappears. Apply twice daily, in the morning and at night.

If an infection develops, appropriate antimicrobial therapy should be instituted.

Betamethasone Dipropionate products should not be used with occlusive dressings.

HOW SUPPLIED:

Betamethasone Dipropionate Cream USP, 0.05% is supplied as follows:	Betamethasone Dipropionate Ointment USP, 0.05% is supplied as follows:	Betamethasone Dipropionate Lotion USP, 0.05% is supplied as follows:
15 g tubes NDC 0168-0055-15	15 g tubes NDC 0168-0056-15	60 mL bottles NDC 0168-0057-60
45 g tubes NDC 0168-0055-46	45 g tubes NDC 0168-0056-46	Shake well before using.

Store at 25°C, excursions permitted between 15° and 30°C. Protect from light and freezing.

E. FOUGERA & CO.
A division of
fougera
PHARMACETICALS INC.
Melville, New York 11747

46291737A
R06/2021
#74

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 45g CREAM CONTAINER

NDC 0168-0055-46

FOUGERA®

BETAMETHASONE
DIPROPIONATE
CREAM USP, 0.05%
(Potency expressed as betamethasone)

Rx only

NET WT 45 grams

NDC 0168-0055-46

Betamethasone Dipropionate Cream USP, 0.05%

(Potency expressed as betamethasone)

FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.

fougera®

USUAL DOSAGE: Apply a thin film of the cream to the affected skin areas once daily. In some cases, twice daily dosage may be necessary. See package insert for full prescribing information.

Store at 25°C, excursions permitted between 15° and 30°C. Protect from light and freezing.

KEEP OUT OF THE REACH OF CHILDREN.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

℞ only

Each gram contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone) in a soft, white, hydrophilic cream of purified water, mineral oil, white petrolatum, polyoxyl 20 cetostearyl ether, cetostearyl alcohol, monobasic sodium phosphate (monohydrate); chlorocresol is present as a preservative. Sodium hydroxide or phosphoric acid solution to adjust pH, if required.

NET WT 45 grams

See crimp of tube for Control No. and Exp. Date.

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A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

46291735A R06/2021

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PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 45g CREAM CARTON

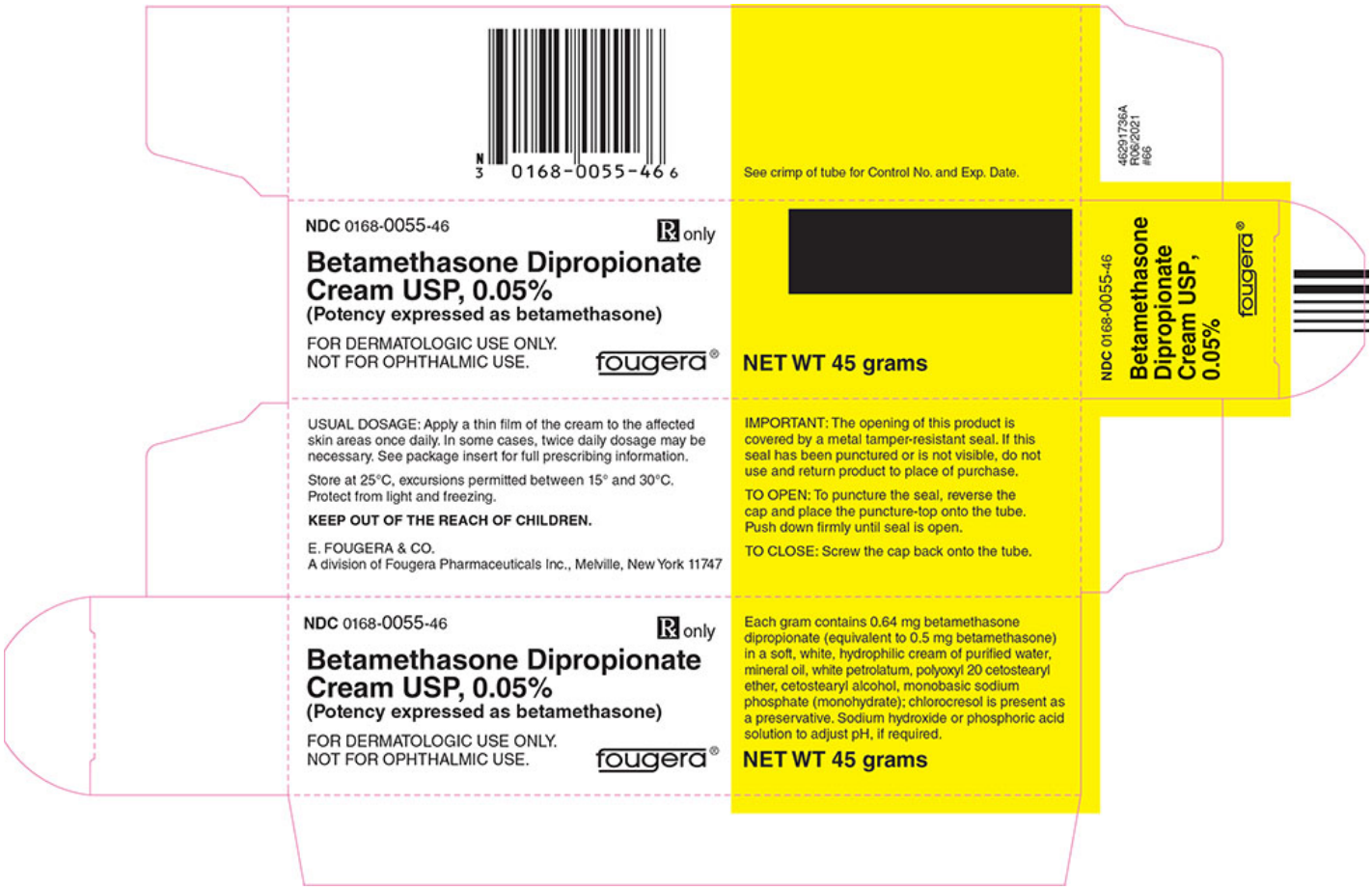
NDC 0168-0055-46

FOUGERA®

BETAMETHASONE DIPROPIONATE
CREAM USP, 0.05%
(Potency expressed as betamethasone)

Rx only

NET WT 45 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15g OINTMENT CONTAINER

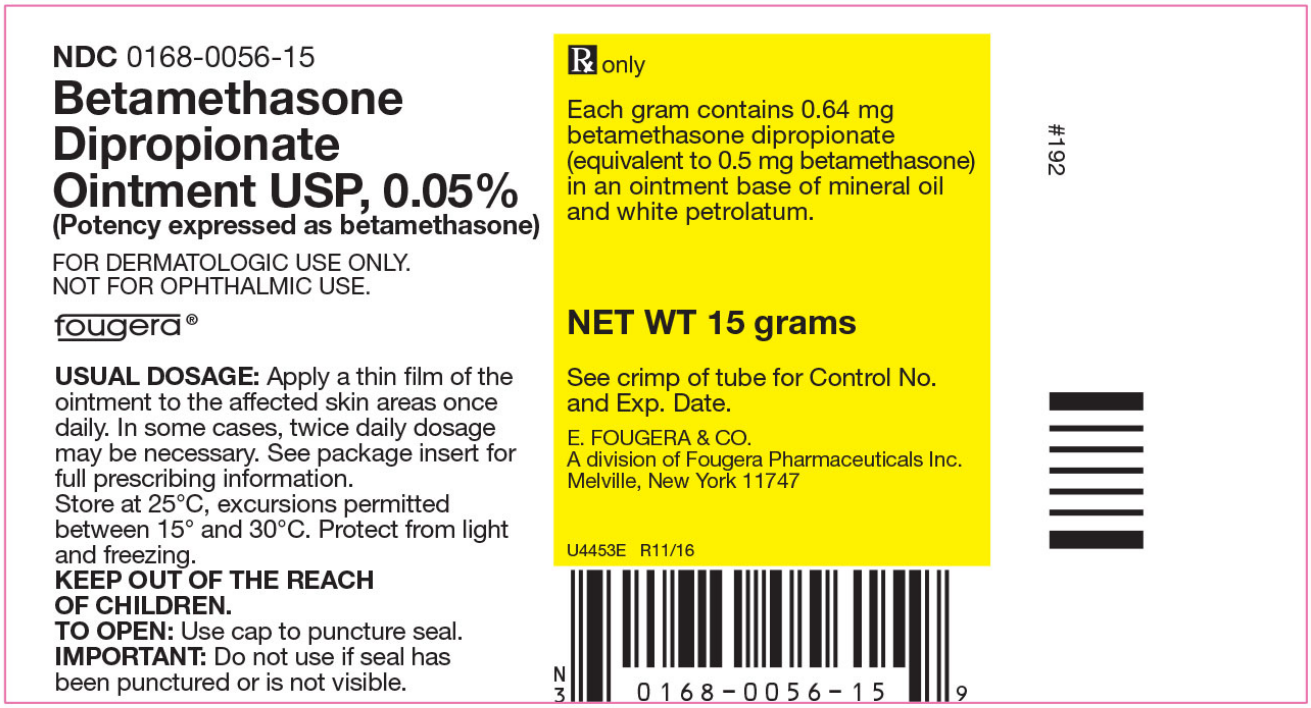
NDC 0168-0056-15

FOUGERA®

BETAMETHASONE
DIPROPIONATE
OINTMENT USP, 0.05%
(Potency expressed as betamethasone)

Rx only

NET WT 15 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15g OINTMENT CARTON

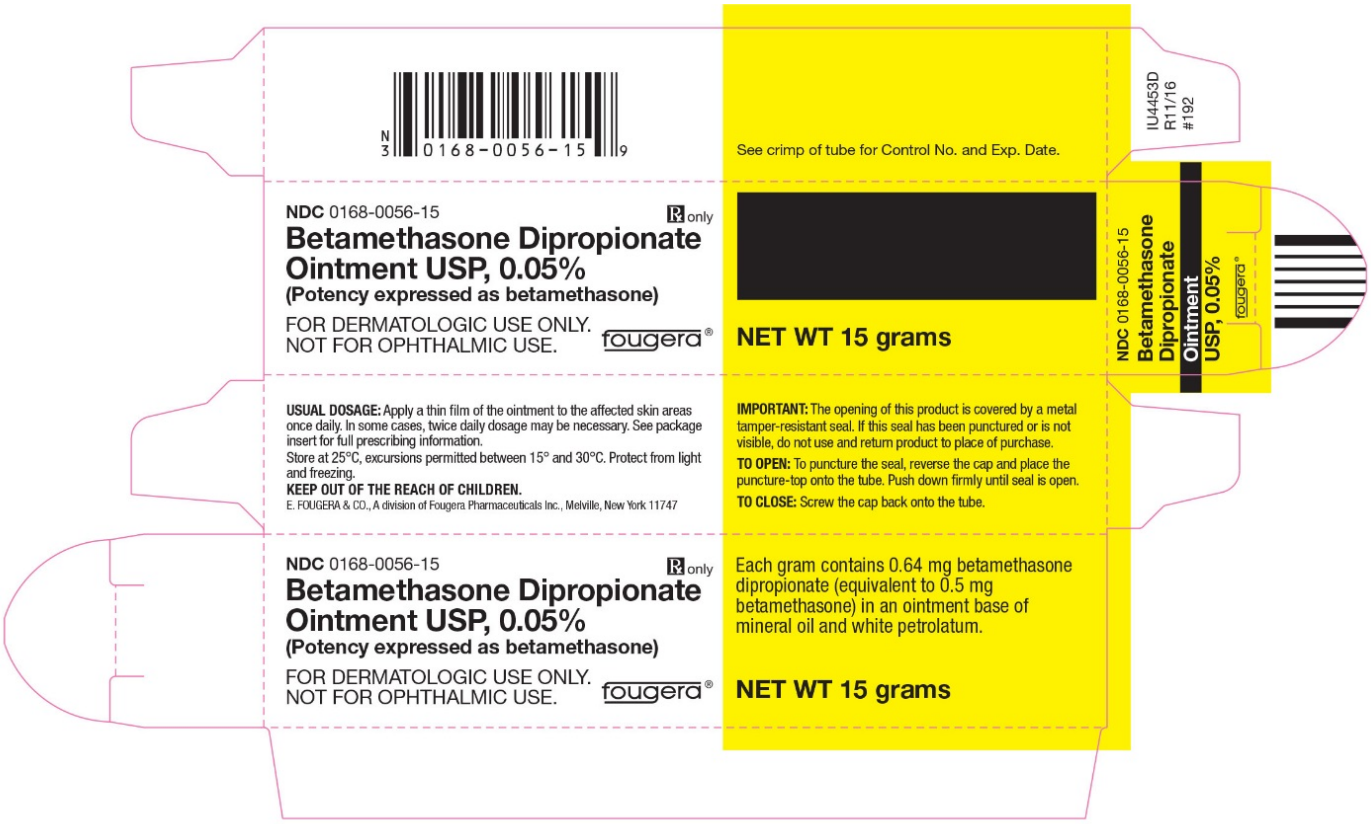
NDC 0168-0056-15

FOUGERA®

BETAMETHASONE DIPROPIONATE
OINTMENT USP, 0.05%
(Potency expressed as betamethasone)

Rx only

NET WT 15 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60mL LOTION CONTAINER

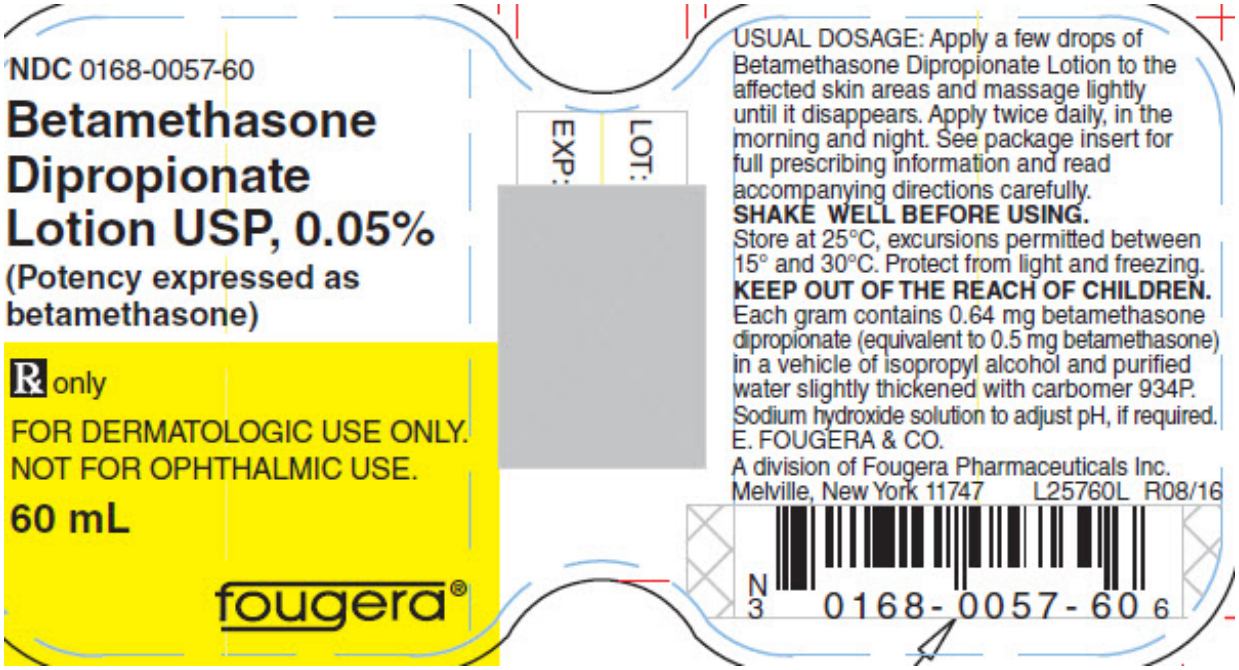
NDC 0168-0057-60

FOUGERA®

BETAMETHASONE DIPROPIONATE LOTION USP, 0.05%
(Potency expressed as betamethasone)

60 mL

Rx only



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60mL LOTION CARTON

NDC 0168-0057-60

FOUGERA®

BETAMETHASONE DIPROPIONATE LOTION USP, 0.05% (Potency expressed as betamethasone)

60 mL

Rx only

BETAMETHASONE DIPROPIONATE

betamethasone dipropionate cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
betamethasone dipropionate (UNII: 826Y60901U) (betamethasone - UNII:9842X06Q6M)	betamethasone	0.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

PETROLATUM (UNII: 4T6H12BN9U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLOROCRESOL (UNII: 36W53O7109)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0055-15	1 in 1 CARTON	06/26/1984	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0168-0055-46	1 in 1 CARTON	06/26/1984	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019137	06/26/1984	

BETAMETHASONE DIPROPIONATE

betamethasone dipropionate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
betamethasone dipropionate (UNII: 826Y60901U) (betamethasone - UNII:9842X06Q6M)	betamethasone	0.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0056-15	1 in 1 CARTON	09/04/1984	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0168-0056-46	1 in 1 CARTON	09/04/1984	
2		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019141	09/04/1984	

BETAMETHASONE DIPROPIONATE

betamethasone dipropionate lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0168-0057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
betamethasone dipropionate (UNII: 826Y60901U) (betamethasone - UNII:9842X06Q6M)	betamethasone	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0057-60	1 in 1 CARTON	08/12/1985	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination		

1		Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070275	08/12/1985	

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

Revised: 2/2022 E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.