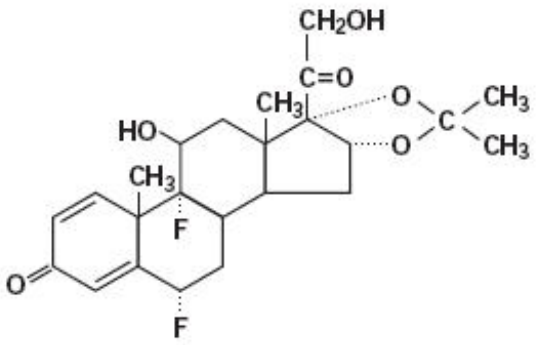
SYNALAR- fluocinolone acetonide cream
SYNALAR - fluocinolone acetonide
Medimetriks Pharmaceuticals, Inc.

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

for initiation of therapy in inflammatory dermatoses.
Rx Only

DESCRIPTION

SYNALAR® (fluocinolone acetonide) Cream 0.025% is intended for topical administration. The active component is the corticosteroid fluocinolone acetonide, which has the chemical name pregna-1,4-diene-3,20-dione,6,9-difluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis (oxy)]-,(6α,11β,16α)-. It has the following chemical structure:



SYNALAR® Cream contains fluocinolone acetonide 0.25 mg/g in a water-washable aqueous base of butylated hydroxytoluene, cetyl alcohol, citric acid, edetate disodium, methylparaben and propylparaben (preservatives), mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, simethicone, stearyl alcohol, water (purified) and white beeswax.

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. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses *(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

SYNALAR® Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteriod-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.

Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing 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.

As with any topical corticosteroid product, prolonged use may produce atrophy of the skin and subcutaneous tissues. When used on intertriginous or flexor areas, or on the face, this may occur even with short-term use.

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 the Patient

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 unless directed by the physician.
4. Patients should report any signs of local adverse reactions, especially under occlusive dressing.
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.

Laboratory Tests

The following tests may be helpful in evaluating the 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 corticosteroidinduced hypothalmic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

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 children 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 with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning	Hypertrichosis	Maceration of the skin
Itching	Acneiform eruptions	Secondary infection
Irritation	Hypopigmentation	Skin atrophy
Dryness	Perioral dermatitis	Striae
Folliculitis	Allergic contact dermatitis	Miliaria

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

SYNALAR® Cream is generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition. In hairy sites, the hair should be parted to allow direct contact with the lesion.

Occlusive dressing may be used for the management of psoriasis or recalcitrant conditions. Some plastic films may be flammable and due care should be exercised in

their use. Similarly, caution should be employed when such films are used on children or left in their proximity, to avoid the possibility of accidental suffocation.

If an infection develops, the use of the occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED

SYNALAR® (fluocinolone acetonide) Cream 0.025% is supplied in

120 g Tube – NDC 43538-900-12

STORAGE

Store at room temperature 15-25°C (59-77°F); avoid freezing and excessive heat above 40°C (104°F).

To report SUSPECTED ADVERSE REACTIONS, contact Medimetriks Pharmaceuticals, Inc. at 1-973-882-7512 or FDA at 1-800-FDA-1088 or www.fda/gov/medwatch.

Manufactured for:

MEDIMETRIKS
PHARMACEUTICALS, INC.

383 Route 46 West, Fairfield, NJ 07004-2402 USA
www.medimetriks.com

Manufactured by: Ferndale Laboratories, Inc., Ferndale, MI 48220

IP027-R3
Rev. 10/2022

PRINCIPAL DISPLAY PANEL - 120 g Tube Carton

R_x Only

NDC 43538-900-12

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

For Topical Use Only
Not For Ophthalmic Use

120 g

MEDIMETRIKS
PHARMACEUTICALS, INC.

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 43538-901-12

For Topical Use Only
Not For Ophthalmic Use

120 g

R_x Only

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

Cream KIT

KIT CONTAINS:

1 - **SYNALAR®**
(fluocinolone acetonide)
Cream, 0.025%
120 g Tube

1 - Keradan® Cream
Net wt. 9 oz. (255 g) Tube

MEDIMETRIKS
PHARMACEUTICALS, INC.

NDC 43538-901-12

For Topical Use Only
Not For Ophthalmic Use

120 g

Rx Only

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120 g
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Cream, 0.025%
Cream KIT

NDC 43538-901-12

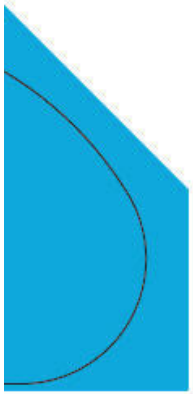
MEDIMETRIKS PHARMACEUTICALS, INC.

Rx Only

SYNAL
(fluocinolor
Cream, 0.0

Usual Dose: A small amo
See package insert for f
Store at room temperatu

Medimetriks Pharm
demands for quality



.AR®
ıe acetonide)
25%

ɔunt should be gently massaged into the affected area two to four times daily, as needed.
ull prescribing information.
ıre 15-25°C (59-77°F); avoid freezing and excessive heat above 40°C (104°F).

Keradan® CREAM

Directions: Apply daily as needed, especially after using soaps and detergents.
Caution: For external use only. Avoid contact with eyes, lips and mucous membranes.
Storage: Store at 15°C–30°C (59°F–86°F). **KEEP OUT OF REACH OF CHILDREN.**
No Animal Testing • Made in USA

ıaceuticals guarantees that this product was manufactured with the highest pharmaceutical control standards, the most desirable ingredients, under strict y and safety, ensuring batch-to-batch quality and use-to-use consistency.

MEDIMETRIKS PHARMACEUTICALS, INC.

For Topical Use Only
Not For Ophthalmic Use

KIT CONTAINS:
1 - SYNALAR® (fluocinolone acetonide) Cream, 0.025% 120 g Tube
1 - Keradan® Cream Net wt. 9 oz. (255 g) Tube

NDC 43538-901-12

℞ Only

120 g

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

Cream KIT

NDC 43538-901-12

Rx Only

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004-2402 USA
Made in USA

Keradan® CREAM

Manufactured for: Medimetriks Pharmaceuticals, Inc.
383 Route 46 West, Fairfield, NJ 07004-2402 USA
Made in USA

IC135-R2

NO VARNISH AREA

Serialization code, Lot # and
Expiration Date imprint goes here

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MEDIMETRIKS PHARMACEUTICALS, INC.

Rx Only 120 g

SYNALAR®
(fluocinolone acetonide)
Cream, 0.025%

Cream KIT

NDC 43538-901-12

For Topical Use Only
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Cream, 0.025%
120 g Tube
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Net wt. 9 oz. (255 g) Tube

SYNALAR

fluocinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
fluocinolone acetonide (UNII: 0CD5FD6S2M) (fluocinolone acetonide - UNII:0CD5FD6S2M)	fluocinolone acetonide	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
cetyl alcohol (UNII: 936JST6JCN)	
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
mineral oil (UNII: T5L8T28FGP)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWUY)	
propylene glycol (UNII: 6DC9Q167V3)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
water (UNII: 059QF0KO0R)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-900-99	6 in 1 CARTON	09/27/2012	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43538-900-12	1 in 1 CARTON	09/27/2012	

2		120 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	NDA012787	09/27/2012	

SYNALAR

fluocinolone acetonide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:43538-901

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-901-12	1 in 1 CARTON	12/15/2012	11/01/2023

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	120 g
Part 2	1 TUBE	255 g

Part 1 of 2

SYNALAR

fluocinolone acetonide cream

Product Information

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
fluocinolone acetonide (UNII: 0CD5FD6S2M) (fluocinolone acetonide - UNII:0CD5FD6S2M)	fluocinolone acetonide	0.25 mg in 1 g

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cetyl alcohol (UNII: 936JST6JCN)	
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
mineral oil (UNII: T5L8T28FGP)	
polyoxyl 20 cetostearyl ether (UNII: YRC528SWJY)	
propylene glycol (UNII: 6DC9Q167V3)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
water (UNII: 059QF0KO0R)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		120 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	NDA012787	12/15/2012	

Part 2 of 2

KERADAN

moisturizing cream

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**water** (UNII: 059QF0KO0R)	
INGR	**cetostearyl alcohol** (UNII: 2DMT128M1S)	
INGR	**medium-chain triglycerides** (UNII: C9H2L21V7U)	
INGR	**glycerin** (UNII: PDC6A3C0OX)	
INGR	**cetyl alcohol** (UNII: 936JST6JCN)	
INGR	**petrolatum** (UNII: 4T6H12BN9U)	
INGR	**polyoxyl 20 cetostearyl ether** (UNII: YRC528SWJY)	

INGR	**caprylyl trisiloxane** (UNII: Q95M2P1KJL)	
INGR	**cyclomethicone 5** (UNII: 0THT5PCI0R)	
INGR	**cyclomethicone 4** (UNII: CZ227117JE)	
INGR	**stearic acid** (UNII: 4ELV7Z65AP)	
INGR	**paraffin** (UNII: I9O0E3H2ZE)	
INGR	**polysorbate 20** (UNII: 7T1F30V5YH)	
INGR	**phenoxyethanol** (UNII: HIE492ZZ3T)	
INGR	**xanthan gum** (UNII: TTV12P4NEE)	
INGR	**cholesterol** (UNII: 97C5T2UQ7J)	
INGR	**allantoin** (UNII: 344S277G0Z)	
INGR	**yellow wax** (UNII: 2ZA36H0S2V)	
INGR	**methylparaben** (UNII: A2I8C7HI9T)	
INGR	**linoleic acid** (UNII: 9KJL21T0QJ)	
INGR	**trolamine** (UNII: 9O3K93S3TK)	
INGR	**edetate disodium** (UNII: 7FLD91C86K)	
INGR	**squalane** (UNII: GW89575KF9)	
INGR	**.alpha.-tocopherol acetate** (UNII: 9E8X80D2L0)	
INGR	**microcrystalline wax** (UNII: XOF597Q3KY)	
INGR	**olive oil** (UNII: 6UYK2W1W1E)	
INGR	**aluminum acetate** (UNII: 80EHD8I43D)	
INGR	**aluminum sulfate** (UNII: 34S289N54E)	
INGR	**calcium acetate** (UNII: Y882YXF34X)	
INGR	**sodium lauroyl lactylate** (UNII: 7243K85WFO)	
INGR	**linolenic acid** (UNII: 0RBV727H71)	
INGR	**hyaluronate sodium** (UNII: YSE9PPT4TH)	
INGR	**CERAMIDE NP** (UNII: 4370DF050B)	
INGR	**CERAMIDE AP** (UNII: F1X8L2B00J)	
INGR	**tocopherol** (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		255 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
COSMETIC		06/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA012787	12/15/2012	11/01/2023

Labeler - Medimetriks Pharmaceuticals, Inc. (019903816)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	ANALYSIS(43538-900) , LABEL(43538-900) , MANUFACTURE(43538-900) , PACK(43538-900)

Revised: 12/2023 Medimetriks Pharmaceuticals, Inc.