XILAPAK- fluocinolone acetonide
SOLUTECH PHARMACEUTICALS LLC

XILAPAK KIT

(NDC 70350-5218-1)

For external use only.
Not for ophthalmic use.

Rx Only

XILAPAK KIT DESCRIPTION

XILAPAK is supplied as 3 components in a *kit*:

- FLUOCINOLONE ACETONIDE TOPICAL SOLUTION USP, 0.01% (NDC 52565-012-59), 60mL
- CETAPHIL CLEANSER (NDC 00299-3921-40), 4 fl oz
- SILICONE TAPE, 1 Roll, 5.5 yards

INDICATION AND USAGE

For the management of hypertrophic tissues, keloid tissues, dermatitis and dermatoses.[1]

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[1] This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease.

DOSAGE AND ADMINISTRATION

Apply Cetaphil Cleanser to the affected area, rub gently and rinse with water. Then apply Fluocinolone Acetonide 0.01% Topical Solution and rub into skin until absorbed. Apply twice a day or as directed by your physician. Cover the affected area with silicone tape at bedtime or as directed by your physician.

WARNINGS

FOR EXTERNAL USE ONLY. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin.

CONTRAINDICATIONS

Do not use if known hypersensitivity to any of the listed ingredients of *any* of the components included in the kit.

PRECAUTIONS

Stop use and ask a doctor if redness or irritation develops. Keep this and all other medications out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PREGNANCY

If pregnant or breast feeding, ask a health professional before use.

Store at 20°-25°C (68° to 77°F); Keep away from heat and flame. Protect from freezing. [See USP

Controlled Room Temperature.]

MANUFACTURED FOR:
SOLUTECH PHARMACEUTICALS LLC
PEORIA, AZ 85345

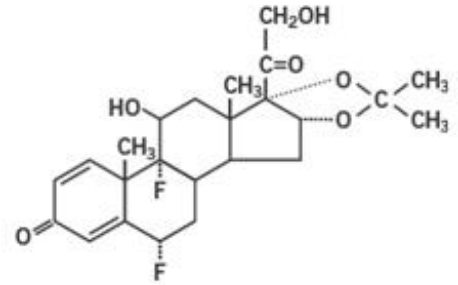
Rx Only

Fluocinolone Acetonide Topical Solution USP, 0.01%

Rx Only

DESCRIPTION

Fluocinolone Acetonide Topical Solution USP, 0.01% 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-dihydroxy16,17[(methylethylidene)bis(oxy)]-, (6α,11β,16α)-. It has the following chemical structure:



Fluocinolone Acetonide Solution USP contains fluocinolone acetonide 0.1 mg/mL in a water-washable base of citric acid and propylene glycol.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic 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 the 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

Fluocinolone Acetonide Topical Solution is 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 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 glycosuria 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 for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped so 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 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 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
Itching
Irritation
Dryness
Folliculitis
Hypertrichosis
Acneiform eruptions
Hypopigmentation
Perioral dermatitis
Allergic contact dermatitis
Maceration of the skin
Secondary infection
Skin atrophy
Striae
Miliaria

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Fluocinolone Acetonide Topical Solution 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.

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

HOW SUPPLIED

Fluocinolone Acetonide Topical Solution 0.01%
60 mL Bottle with applicator tip - NDC 52565-012-59

STORAGE

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

Teligent Pharma, Inc.
Buena, New Jersey 08310
PI012
Iss. 11/12

Cetaphil Cleanser 4 fl oz

Galderma Laboratories, L.P.

Product details

For All Skin Types

- Mild, non-irritating formula
- Softens as it cleans
- Non-comedogenic/fragrance free
- Dermatologist recommended

This gentle, soap-free cleanser was originally formulated for dermatologists, specifically for everyday cleansing of even the most sensitive skin.

- Soothing, non-irritating cleanser ideal for face, hands and body
- Helps skin retain needed moisture
- Rinses easily and leaves skin feeling soft, smooth and healthy

Ingredients: Water, Cetyl Alcohol, Propylene Glycol, Sodium Lauryl Sulfate, Stearyl Alcohol, Methylparaben, Propylparaben, Butylparaben

Cetaphil Cleanser is easy to use:

Directions for use with water: Apply cleanser and gently massage into skin. Rinse.

Directions for use without Water: Apply a liberal amount to the skin and rub gently. Remove excess with a soft cloth, leaving a thin film of CETAPHIL on the skin.

Warnings

For external use only.

Ask a doctor or pharmacist if it is safe for you to use this medicine if you have:

- Deep wounds or open sores;
- Swelling, warmth, redness, oozing, or bleeding on the site of application;
- Large areas of skin irritation;
- Any type of allergy; or
- If you are pregnant or breast-feeding.

Contraindications

Contraindicated in patients with known hypersensitivity to any of the listed ingredients.

Side Effects

No *common* side effects have been reported with this product. Stop use and ask a doctor if rash occurs.

Silicone Tape, 1 Roll, 5.5 yards

Description

Silicone tape is a silicone blended tape. This tape is designed to not harm the skin when it is being removed. Most tapes pull the skin and the small hairs, causing unnecessary damage. This Silicone tape has a paper blended backing that allows a gentle, but strong adhesion to the skin that remains constant. Most tapes increase their adhesion over time, which increases the damage when they are removed.

The silicone tape can be re-positioned without losing any of its tacky qualities. The gentle adhesion does not lower the quality of the hold either. This tape is adhesive enough that it can be worn in the shower without losing effectiveness.

Purpose

For alleviating tension on the scar and its surrounding skin. Tension on a wound and scar is known to increase scar tissue formation.

Because of its adherence, silicone tape reduces tension (e.g. tear and stretch) along the incision line or wound which is known to minimize the degree of scarring in terms of spreading or thickening.

Warnings

FOR EXTERNAL USE ONLY. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin. Do not use if you have known hypersensitivity to silicone

Precautions

Stop use and ask a doctor if redness or irritation or rash develops. Keep out of reach of children.

Directions

Apply to the affected area as directed by your physician.

PRINCIPAL DISPLAY PANEL - Kit Carton

Solutech
PHARMACEUTICALS

XILAPAK KIT

NDC 70350-5218-1

RX ONLY

XILAPAK

fluocinolone acetonide kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-5218

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70350-5218-1	1 in 1 CARTON	11/01/2017	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, WITH APPLICATOR	60 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

FLUOCINOLONE ACETONIDE

fluocinolone acetonide solution

Product Information	
Item Code (Source)	NDC:52565-012
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUOCINOLONE ACETONIDE (UNII: 0CD5FD6S2M) (FLUOCINOLONE ACETONIDE - UNII:0CD5FD6S2M)	FLUOCINOLONE ACETONIDE	0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52565-012-59	1 in 1 CARTON		
		60 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a		

1		60 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA015296	11/27/2012	

Part 2 of 2

CETAPHIL CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) rinse

Product Information

Item Code (Source)	NHRIC:0299-3921
Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**Water** (UNII: 059QF0KO0R)	
INGR	**CETYL ALCOHOL** (UNII: 936JST6JCN)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	
INGR	**SODIUM LAURYL SULFATE** (UNII: 368GB5141J)	
INGR	**STEARYL ALCOHOL** (UNII: 2KR89I4H1Y)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0299-3921-40	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA015296	11/01/2017	

Labeler - SOLUTECH PHARMACEUTICALS LLC (080040396)

Revised: 11/2017 SOLUTECH PHARMACEUTICALS LLC