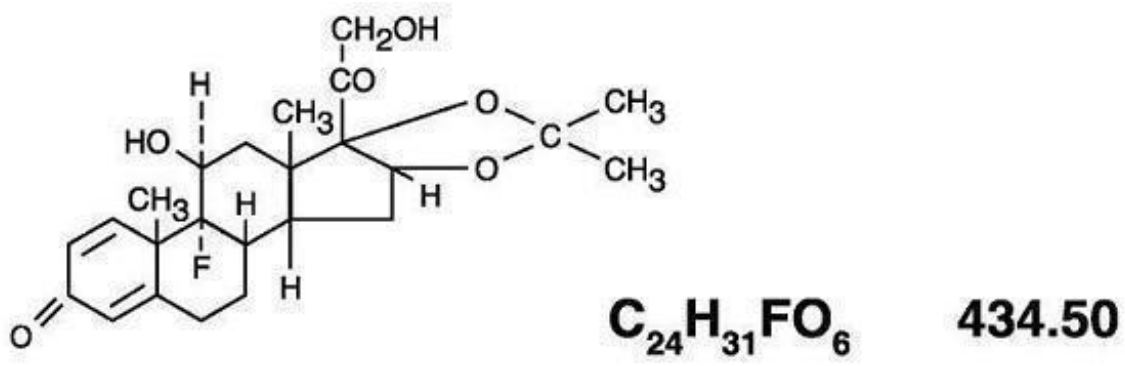
SCARZEN- triamcinolone acetonide, dimethicone
Village Pharma LLC

Scarzen
(triamcinolone acetonide cream, dimethicone lotion and silicone tape)
Rx Only

Triamcinolone Acetonide Cream USP (0.1%)

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents. Triamcinolone acetonide is designated chemically as pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene) bis (oxy)]-,(11ß,16α)-. $C_{24}H_{31}FO_6$, and M.W. of 434.51; CAS Reg. No. 76-25-5. Its structural formula is:



Each gram of 0.1% Triamcinolone Acetonide Cream USP contains 1 mg triamcinolone acetonide, in a washable cream base of cetyl alcohol, cetyl esters wax, glycerin, glyceryl monostearate, isopropyl palmitate, polysorbate-60, propylene glycol, purified water, sorbic acid, and sorbitan monostearate.

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 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. Corticosteriods 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

Triamcinolone acetonide cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Triamcinolone acetonide cream is 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.

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 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 not 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, Cushings'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

Topical corticosteroids are generally applied to the affected area as a thin film from two to three times daily depending on the severity of the condition.

Occlusive dressing may be used for the management of psoriasis or recalcitrant conditions.

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

HOW SUPPLIED

Triamcinolone acetonide cream USP 0.1% is supplied in
80 g tube NDC 45802-064-36

Store at 20-25°C (68°-77°F) [see USP Controlled Room Temperature].

Avoid excessive heat. Protect from freezing.

Skin Repair Complex (Dimethicone 5.0%)

Drug Facts

Uses

■ temporarily protects and helps relieve chapped or cracked skin

Warnings

- For external use only.
- Avoid contact with eyes.

Stop use and ask a doctor if

■ condition worsens
■ symptoms last more than 7 days or clear up and occur again within a few days

Do not use on deep or puncture wounds, animal bites or serious burns.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Cleanse the affected area and allow to dry. Apply as needed.

Other information

■ protect from freezing ■ avoid excessive heat

Silicone Tape

Uses
• To be applied to wounds or scars as a protective silicone barrier.
• As a dressing for abrasions, surgical wounds, donor sites, lacerations, ulcers, skin tears, superficial partial thickness burns, venous leg ulcers.
• As a dressing/securement for IV related uses, pressure ulcers, skin care, and wound care

Precautions
• Do not use if you are allergic to silicone
• Keep out of reach of children

Directions for use
• Apply tape to wound or scar as needed or as directed by your physician. Remove tape, wash area, and apply new tape at least every 24 hours.

PRINCIPAL DISPLAY

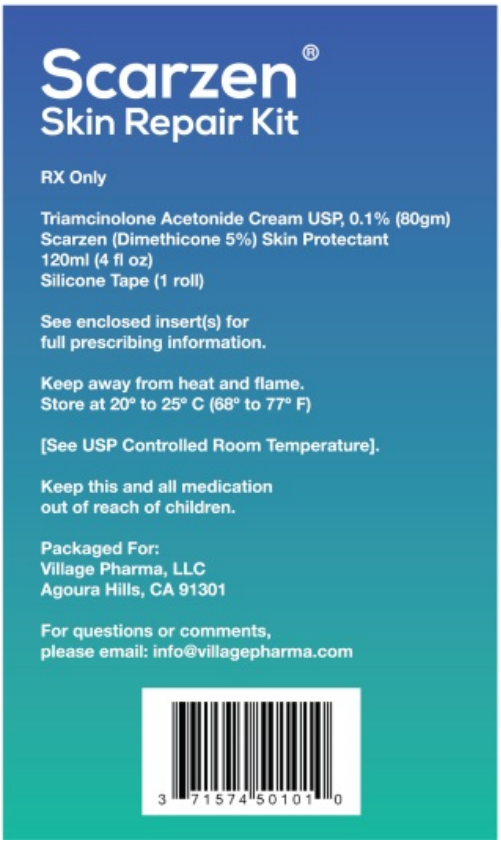
Scarzen (triamcinolone acetonide cream, dimethicone cream and silicone tape)

Rx only

Packaged in the USA for:
Village Pharma LLC
Agoura Hills, CA 91301

For questions or information
email: info@villagepharma.com

(kit carton)



SCARZEN

triamcinolone acetonide, dimethicone kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71574-501

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71574-501-01	1 in 1 PACKAGE; Type 0: Not a Combination Product	07/02/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	80 g
Part 2	1 BOTTLE	120 mL

Part 1 of 2

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information	
Item Code (Source)	NDC:45802-064
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	1 mg in 1 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-064-36	1 in 1 BOX		
1		80 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
ANDA	ANDA086413		

Part 2 of 2

SCARZEN

dimethicone lotion

Product Information	
Item Code (Source)	NDC:71574-500
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	50 mg in 1 mL

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

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
GINGER (UNII: C5529G5JPQ)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYALURONIC ACID (UNII: S270N0TRQY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PANTOTHENIC ACID (UNII: 19F5HK2737)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71574-500-72	1 in 1 BOX		
1		120 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
OTC monograph final	part347	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088042	05/11/2016	

Labeler - Village Pharma LLC (080749749)

Registrant - Village Pharma LLC (080749749)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	MANUFACTURE(71574-501)

Revised: 12/2019 Village Pharma LLC