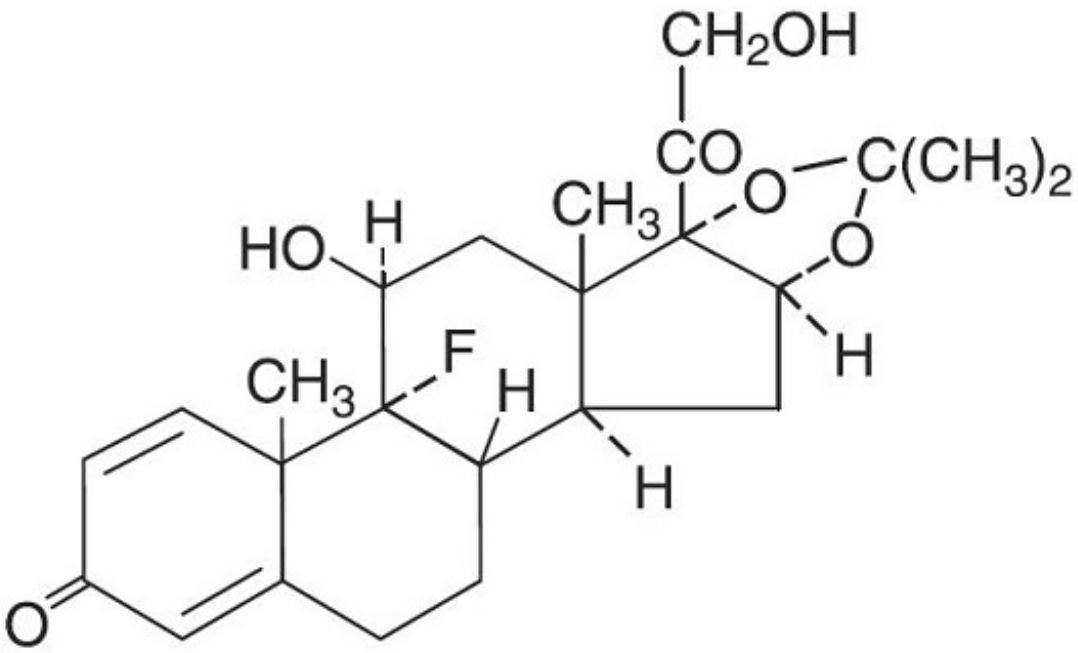
TRIAMVEX- triamcinolone acetonide
Skya Health, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Triamvex Kit

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Triamcinolone acetonide is a member of this class. Chemically triamcinolone acetonide is pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16, 17-[(1-methylethylidene) bis(oxy)]-(11β16α) Its structural formula is:



Each gram of Triamcinolone Acetonide Cream USP, 0.1% contains 1 mg triamcinolone acetonide USP in a cream base consisting of purified water, emulsifying wax, mineral oil, propylene glycol, sorbitol solution, cetyl palmitate, sorbic acid, and potassium sorbate.

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. 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 & 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.

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 & 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, and miliaria.

OVERDOSAGE

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

DOSAGE & ADMINISTRATION

Topical corticosteroids are generally applied to the affected area as a thin film two to four times daily for the 0.025% strength and two or three times daily for the 0.1% and 0.5% strength depending on the severity of the condition.

Occlusive dressings 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

Triamcinolone Acetonide Ointment USP, 0.1%, 80 g - (1 Tube)

80 grams tube NDC 67877-317-80

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

Avoid excessive heat. Protect from freezing.

PRINTED IN USA

Packaged by:
Skya Health, LLC.
Corona, CA 92882
Questions or Comments
Call: 866-759-2669

PRINCIPAL DISPLAY PANEL - Label

NDC: 73086-100-08

TRIAMVEX™

Rx Only

Kit Includes:
- Triamcinolone Acetonide Ointment USP, 0.1%, 80 g - (1 Tube)
- Silicone Tap Roll - (1 Roll)
- Sterile Gauze Pads - (20 count)

Triamcinolone Acetonide Cream USP
Each gram contains 1mg Triamcinolone Acetonide USP in a cream base consisting of purified water, emulsifying wax, mineral oil, propylene glycol, sorbitol solution, cetyl palmitate and potassium sorbate.

Usual Dosage: 2 to 3 applications daily. See package insert for full prescribing information.

TO OPEN: Use cap to puncture seal. **IMPORTANT:** Do not use if seal has been punctured or is not visible.

See enclosed insert for full prescribing information.

store at 20º to 25º C (68º to 77º F)
[see USP Controlled Room Temperature].

Keep this and all medication out of reach of children.

GTIN: 00373086100088
Lot. No: XXXXXX
Exp. XXXXXX

S/N:XXXXXXXX

Rev.A 4125

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Skya
Health

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GTIN: 00373086100088
Lot. No: XXXXXX
Exp. XXXXXX
S/N: XXXXXXXX

Rev.A 4125

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Corona, CA 92882
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TRIAMVEX

triamcinolone acetonide kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73086-100

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73086-100-08	1 in 1 KIT; Type 0: Not a Combination Product	06/13/2025	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 TUBE	80 g

Part 1 of 1

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information	
Item Code (Source)	NDC:67877-251
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

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

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
SORBIC ACID (UNII: X045WJ989B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67877-251-80	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	ANDA088042	06/13/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/13/2025	

Labeler - Skya Health, LLC (117039304)

Establishment

Name	Address	ID/FEI	Business Operations
Skya Health, LLC		117039304	MANUFACTURE(73086-100, 67877-251)

Revised: 5/2025 Skya Health, LLC