

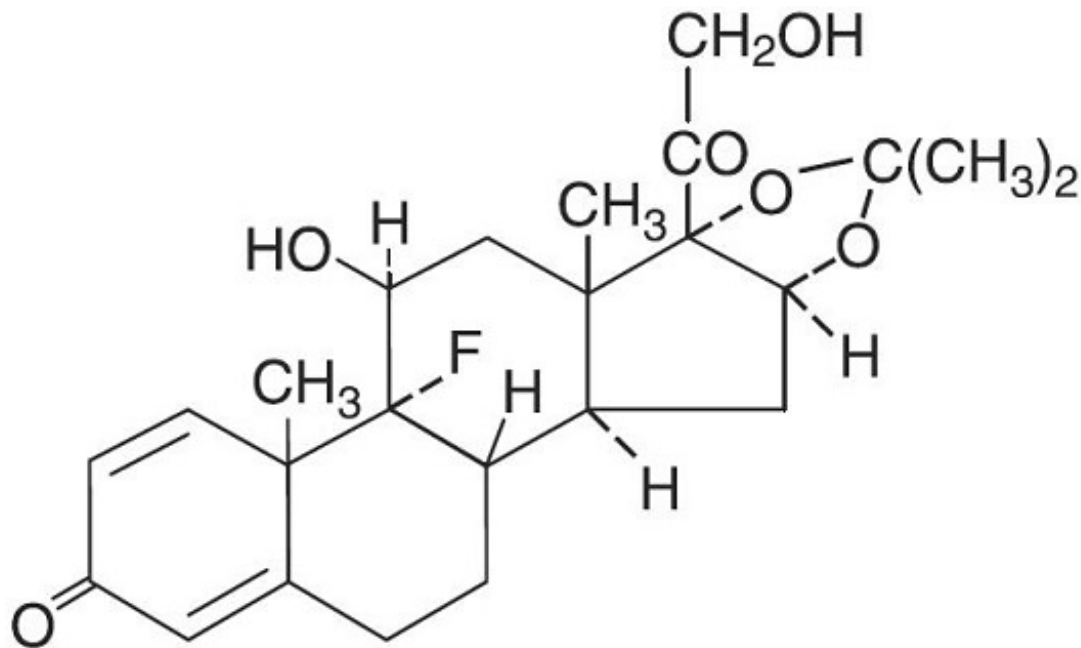
**TRIADERMEX- triamcinolone acetonide**  
**Florrx Pharmaceutical**

*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.*

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**Triadermex 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 prena-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16, 17-[(1-methylethylidene) bis(oxy)]-(11 $\beta$ 16 $\alpha$ ) 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.

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.

## **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

## **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 Cream 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:  
Oncora Pharma LLC

Dallas TX 75228

Questions or Comments  
Call: (833) 242-4493

## **PRINCIPAL DISPLAY PANEL - Label**

NDC:84460-807-01

***Triadermex***<sup>TM</sup>

### **Rx Only**

Kit Includes:

- Triamcinolone Acetonide Cream USP, 0.1%, 80 g - (1 Tube)
- Silicone Tape Roll - (1 Roll)
- Sterile Gauze Pads - (20 count)

### **Triamcinolone Acetonide Cream USP**

Each gram 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.

**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 20° to 25° C (68° to 77° F)  
[see USP Controlled Room Temperature].

**Keep this and all medication out of reach of children.  
For external use only.  
Not for ophthalmic use.**

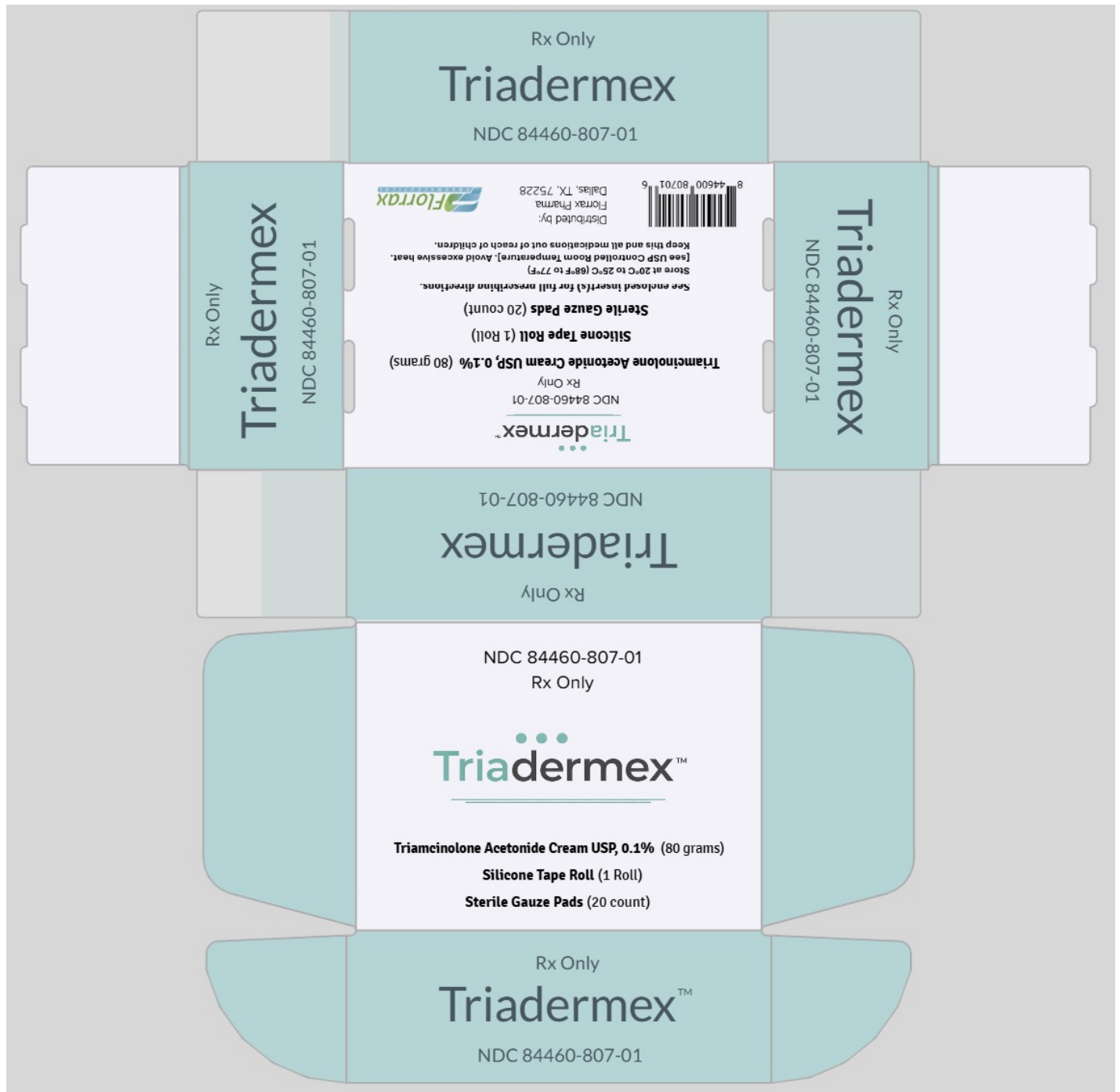
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pdp

# TRIADERMEX

triamcinolone acetonide kit

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:84460-100
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84460-100-08	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

<b>Item Code (Source)</b>	NDC:67877-251
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<b>Route of Administration</b>	TOPICAL
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## 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** - Florrax Pharmaceutical (119257612)

## Establishment

Name	Address	ID/FEI	Business Operations
Skya Health, LLC		117039304	manufacture(84460-100, 67877-251)

Revised: 4/2026

Florrax Pharmaceutical