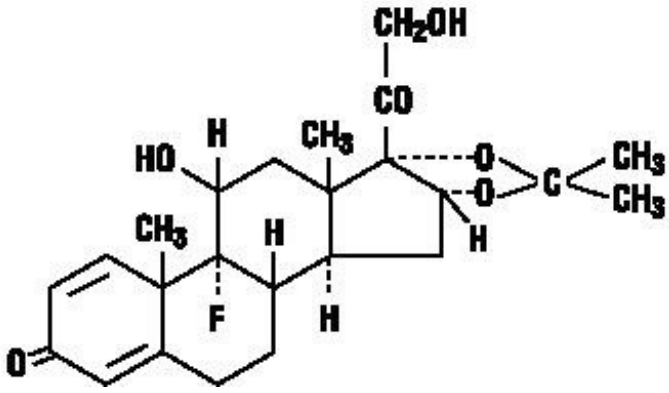
KENALOG- triamcinolone acetonide aerosol, spray
Sun Pharmaceutical Industries, Inc.

KENALOG® SPRAY
Triamcinolone Acetonide Topical Aerosol, USP
(0.147 mg/g)
Rx only
For dermatologic use only
Not for ophthalmic use

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include triamcinolone acetonide. Triamcinolone acetonide is designated chemically as 9-fluoro-11β, 16α, 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17-acetal with acetone. The structural formula is:



$C_{24}H_{31}FO_6$, MW 434.50

A two-second application, which covers an area approximately the size of the hand, delivers an amount of triamcinolone acetonide not exceeding 0.2 mg. After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

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.

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

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP) is indicated for 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 preparations.

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 any 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, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach.

Recovery of HPA axis function and thermal homeostasis are 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 the Patient

Patients using Kenalog Spray 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 and inhalation of the spray.
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.
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.
6. Do not use Kenalog Spray on the underarms or groin areas unless directed by your physician.
7. If no improvement is seen within 2 weeks, contact your physician.
8. Do not use other corticosteroid-containing products while using Kenalog Spray without first consulting your physician.
9. Kenalog Spray is flammable. Avoid heat, flames or smoking when applying Kenalog Spray.

Laboratory Tests

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

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 showed negative results.

Pregnancy: Teratogenic Effects

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.

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 (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, General**).

DOSAGE AND ADMINISTRATION

Directions for use of the spray can are provided on the label. The preparation may be applied to any area of the body, but when it is sprayed about the face, care should be taken to see that the eyes are covered, and that inhalation of the spray is avoided.

Spray is flammable; avoid heat, flame or smoking when using this product.

Three or four applications daily of Kenalog Spray (Triamcinolone Acetonide Topical Aerosol) are generally adequate.

HOW SUPPLIED

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP) is a clear, colorless liquid that is practically free from visible impurities. It has an odor characteristic of ethanol. It is supplied as follows:

63 g (NDC 10631-093-62) aerosol can.

100 g (NDC 10631-093-07) aerosol can.

Storage and Handling

Store at room temperature; avoid excessive heat. Contents under pressure; do not puncture or incinerate. Keep out of reach of children.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured by:

DPT Laboratories Inc.

San Antonio, TX 78215

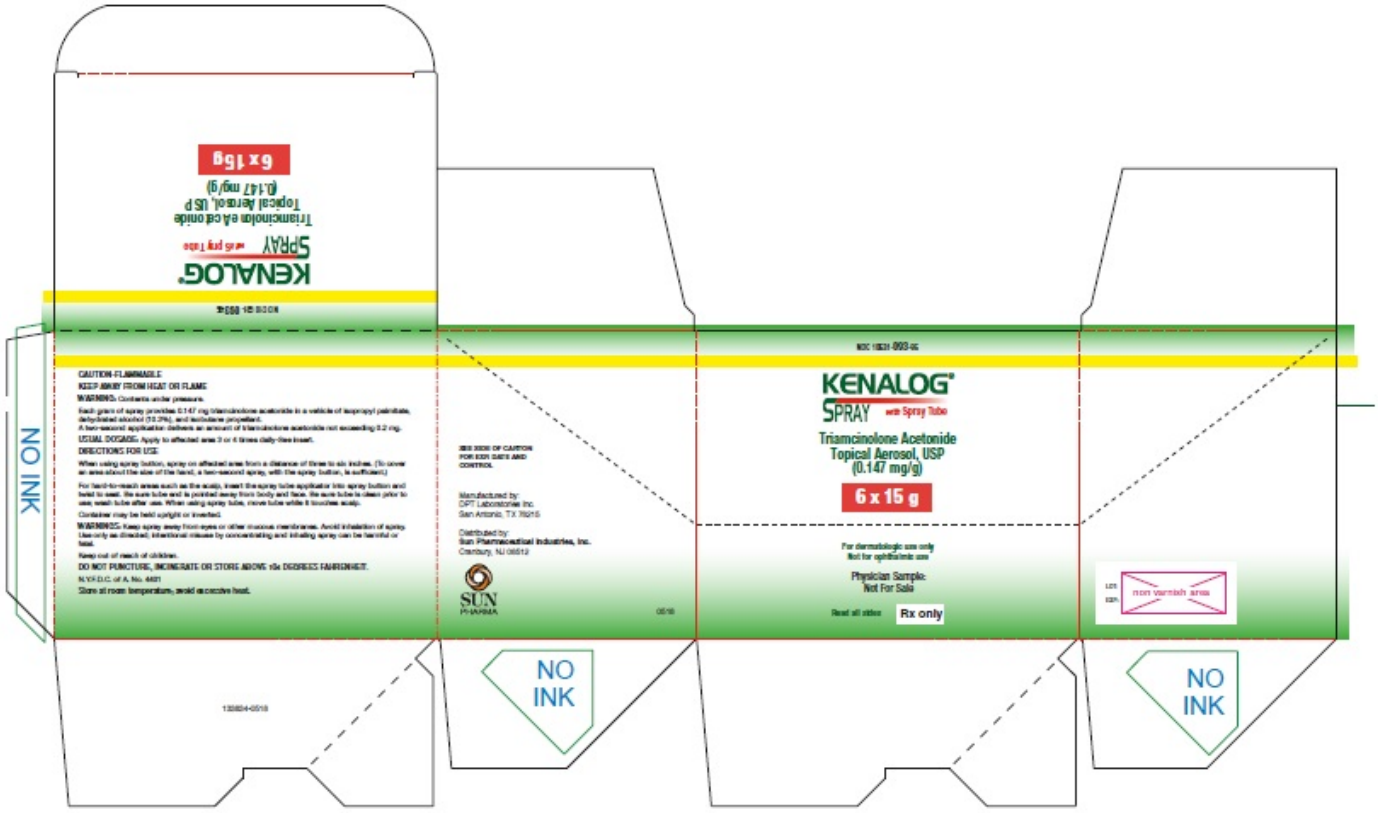
Distributed by:

Sun Pharmaceutical Industries, Inc.

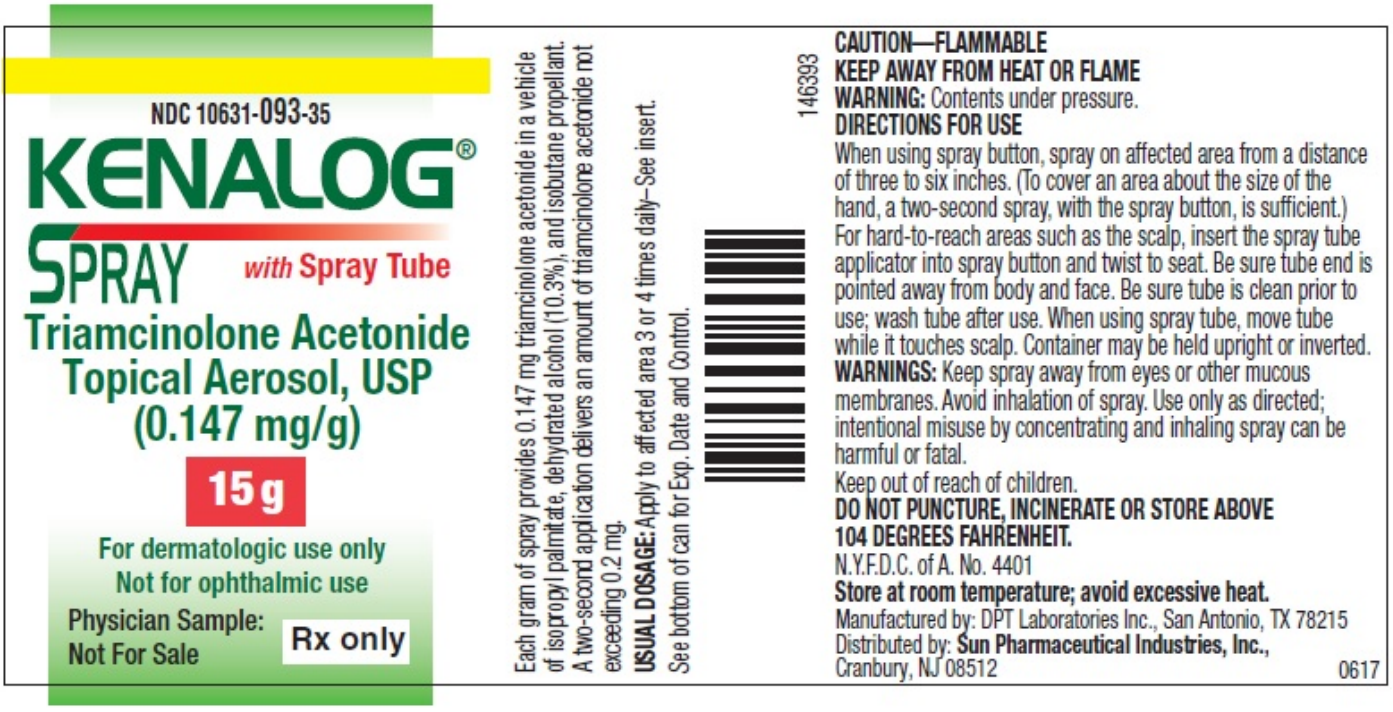
Cranbury, NJ 08512

Revised May 2018

Package/Label Display Panel- 15 g carton



Package/Label Display Panel- 15 g Label



PACKAGE LABEL- 63 g Label

NDC 10631-093-62

KENALOG®

SPRAY *with* Spray Tube

Triamcinolone Acetonide Topical Aerosol, USP (0.147 mg/g)

63 g

For dermatologic use only
Not for ophthalmic use

Rx only

146394

Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant. A two-second application delivers an amount of triamcinolone acetonide not exceeding 0.2 mg.

USUAL DOSAGE: Apply to affected area 3 or 4 times daily–See insert.

See bottom of can for Exp. Date and Control.

CAUTION—FLAMMABLE
KEEP AWAY FROM HEAT OR FLAME

WARNING: Contents under pressure.

DIRECTIONS FOR USE

When using spray button, spray on affected area from a distance of three to six inches. (To cover an area about the size of the hand, a two-second spray, with the spray button, is sufficient.)

For hard-to-reach areas such as the scalp, insert the spray tube applicator into spray button and twist to seat. Be sure tube end is pointed away from body and face. Be sure tube is clean prior to use; wash tube after use. When using spray tube, move tube while it touches scalp. Container may be held upright or inverted.

WARNINGS: Keep spray away from eyes or other mucous membranes. Avoid inhalation of spray. Use only as directed; intentional misuse by concentrating and inhaling spray can be harmful or fatal.

Keep out of reach of children.

DO NOT PUNCTURE, INCINERATE OR STORE ABOVE 104 DEGREES FAHRENHEIT.

N.Y.F.D.C. of A. No. 4401

Store at room temperature; avoid excessive heat.

Manufactured by: DPT Laboratories Inc., San Antonio, TX 78215

Distributed by: **Sun Pharmaceutical Industries, Inc.**, Cranbury, NJ 08512

DOT 2P M5655 0617

N 3 10631 09362 4

Carton Size : 1-5/8" x 1-5/8" x 5-7/8"
Track : A20/10/2011, A24/10/2011,
A02/11/2011, R09/11/11, A02/12/2011
A30/08/2012, A17/06/2017, A21/06/2017

NDC 10631-093-07

KENALOG®
SPRAY *with Spray Tube*

Triamcinolone Acetonide Topical Aerosol, USP (0.147 mg/g)

100 g

For dermatologic use only
Not for ophthalmic use

Rx only

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USUAL DOSAGE: Apply to affected area 3 or 4 times daily–See insert.

See bottom of can for Exp. Date and Control.

146395

CAUTION—FLAMMABLE

KEEP AWAY FROM HEAT OR FLAME

WARNING: Contents under pressure.

DIRECTIONS FOR USE

When using spray button, spray on affected area from a distance of three to six inches. (To cover an area about the size of the hand, a two-second spray, with the spray button, is sufficient.)

For hard-to-reach areas such as the scalp, insert the spray tube applicator into spray button and twist to seat. Be sure tube end is pointed away from body and face. Be sure tube is clean prior to use; wash tube after use. When using spray tube, move tube while it touches scalp. Container may be held upright or inverted.

WARNINGS: Keep spray away from eyes or other mucous membranes. Avoid inhalation of spray. Use only as directed; intentional misuse by concentrating and inhaling spray can be harmful or fatal.

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N.Y.F.D.C. of A. No. 4401

Store at room temperature; avoid excessive heat.

Manufactured by:
DPT Laboratories Inc.
San Antonio, TX 78215
Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

DOT 2P M6556 0617

NDC 10631-093-07 5

KENALOG

triamcinolone acetonide aerosol, spray

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:10631-093
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	0.147 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ISOBUTANE (UNII: BXR49TP611)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10631-093-62	63 g in 1 CAN; Type 0: Not a Combination Product	05/19/2009	
2	NDC:10631-093-07	100 g in 1 CAN; Type 0: Not a Combination Product	05/19/2009	
3	NDC:10631-093-96	6 in 1 CARTON	05/19/2009	
3	NDC:10631-093-35	15 g in 1 CAN; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA012104	05/19/2009	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	MANUFACTURE(10631-093)

Revised: 11/2018 Sun Pharmaceutical Industries, Inc.