FLUOCINOLONE ACETONIDE- fluocinolone acetonide oil
Padagis Israel Pharmaceuticals Ltd

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FLUOCINOLONE ACETONIDE TOPICAL OIL safely and effectively. See full prescribing information for FLUOCINOLONE ACETONIDE TOPICAL OIL.
FLUOCINOLONE ACETONIDE topical oil (body oil)
Initial U.S. Approval: 1988

INDICATIONS AND USAGE

Fluocinolone acetonide topical oil is a corticosteroid indicated for the topical treatment of:

- atopic dermatitis in adults (1)
- moderate to severe atopic dermatitis in pediatric patients 3 months of age and older (1)

DOSAGE AND ADMINISTRATION

- Fluocinolone acetonide topical oil is not for oral, ophthalmic, or intravaginal use. (2.1)
- Do not use on face or intertriginous areas. (2.1)
- Adult patients: Apply to affected areas 3 times daily. (2.2)
- Pediatric patients: Moisten skin and apply to affected areas twice daily for up to 4 weeks. (2.3)

DOSAGE FORMS AND STRENGTHS

Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) is a topical oil containing 0.01% fluocinolone acetonide supplied in bottles containing 4 fluid ounces. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- Endocrine System Adverse Reactions:
  - Topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glucosuria. (5.1)
  - Pediatric patients may be more susceptible to systemic toxicity from equivalent doses. (5.1, 8.4)
  - Systemic absorption may require evaluation for HPA axis suppression. Potent corticosteroids use on large areas, prolonged use, occlusive use, altered skin barrier, liver failure, and young age may increase systemic absorption. Modify use should HPA axis suppression develop. (5.1)
- Local Adverse Reactions: Local adverse reactions may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation, and allergic contact dermatitis and may be more likely with occlusive use or more potent corticosteroids. (5.2, 6.1)
- Ophthalmic Adverse Reactions: May increase the risks of glaucoma and posterior subcapsular cataract. Avoid contact of fluocinolone acetonide topical oil with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation. (5.3)

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) were cough (20%), rhinorrhea (13%), pyrexia (10%), telangiectasia (7%), nasopharyngitis (7%), and hypopigmentation (7%). (6.1, 6.2)
To report SUSPECTED ADVERSE REACTIONS, contact Padagis® at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Fluocinolone acetonide topical oil is indicated for the topical treatment of:

- atopic dermatitis in adults
- moderate to severe atopic dermatitis in pediatric patients 3 months of age and older

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Fluocinolone acetonide topical oil is for topical use only. Not for oral, ophthalmic, or

intravaginal use.

Apply the least amount of fluocinolone acetonide topical oil needed to cover the affected areas. Discontinue use when control of disease is achieved within 2 weeks or contact the healthcare provider if no improvement is seen within 2 weeks.

Do not use on the face, axillae, or groin unless directed by the healthcare provider. Do not apply to intertriginous areas due to the increased risk of local adverse reactions *[see Adverse Reactions (6) and Use in Specific Populations (8.4)]*.

Do not apply to the diaper area; diapers or plastic pants may constitute occlusive use *[see Warnings and Precautions (5.1)]*.

2.2 Recommended Dosage in Adults

Apply fluocinolone acetonide topical oil as a thin film to the affected areas **three times daily**.

2.3 Recommended Dosage in Pediatric Patients

Moisten skin and apply fluocinolone acetonide topical oil as a thin film to the affected areas **twice daily for up to four weeks**.

3 DOSAGE FORMS AND STRENGTHS

Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) is a topical oil containing 0.01% fluocinolone acetonide, supplied in bottles containing 4 fluid ounces.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Endocrine System Adverse Reactions

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. Cushing’s syndrome, hyperglycemia, and glucosuria can result from systemic absorption of topical corticosteroids.

HPA axis suppression and Cushing’s syndrome have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and subnormal response to ACTH stimulation. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios *[see Use in Specific Populations (8.4)].*

Conditions which increase systemic absorption include the use of more potent corticosteroids, use over large surface areas, use over prolonged periods, use of occlusive dressings, altered skin barrier, liver failure, and young age. Use of more than one corticosteroid-containing product at the same time may increase total systemic

corticosteroid exposure. Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. The ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, reduce the frequency of application or discontinue fluocinolone acetonide topical oil, or substitute with a less potent corticosteroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids.

5.2 Local Adverse Reactions

Local adverse reactions may occur with use of topical corticosteroids, including fluocinolone acetonide topical oil, and may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria *[see Adverse Reactions (6.1)].*

5.3 Ophthalmic Adverse Reactions

Use of topical corticosteroids may increase the risks of glaucoma and posterior subcapsular cataract. Glaucoma and cataracts have been reported in postmarketing experience with the use of topical corticosteroid products. Avoid contact of fluocinolone acetonide topical oil with eyes. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.4 Allergic Contact Dermatitis

Use of topical corticosteroids can cause allergic contact dermatitis. Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

5.5 Concomitant Skin Infections

Use of topical corticosteroids may delay healing or worsen concomitant skin infections. Treat concomitant skin infections with an appropriate antimicrobial agent. If the infection persists unchanged, discontinue fluocinolone acetonide topical oil until the infection has been adequately treated.

5.6 Use in Peanut-Sensitive Individuals

Use caution in prescribing fluocinolone acetonide topical oil for peanut-sensitive individuals *[see Description (11)].*

Should signs of hypersensitivity present (wheal and flare reactions, pruritus, or other manifestations), or should disease exacerbations occur, discontinue fluocinolone acetonide topical oil immediately and institute appropriate therapy.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in more detail in other sections of the labeling:

- Endocrine System Adverse Reactions *[see Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*
- Local Adverse Reactions *[see Warnings and Precautions (5.2)]*
- Ophthalmic Adverse Reactions *[see Warnings and Precautions (5.3)]*

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

An open-label trial was conducted in 58 pediatric subjects 2 years to 12 years of age with moderate to severe atopic dermatitis to evaluate the safety of fluocinolone acetonide topical oil when applied to the face twice daily for 4 weeks. Adverse reactions reported by ≥2% of pediatric subjects treated with fluocinolone acetonide topical oil are shown in Table 1.

Table 1: Adverse Reactions in ≥2% of Pediatric Subjects 2 Years to 12 Years of Age with Moderate to Severe Atopic Dermatitis, Treated with Fluocinolone Acetonide Topical Oil (Body Oil), N=58

Adverse Reaction (AR)*	n (%)	Day 14	Day 28**	Day 56***
Any AE	15 (26)	6 (10)	7 (12)	7 (12)
Telangiectasia	5 (9)	3 (5)	4 (7)	2 (4)
Erythema	3 (5)			3 (5)
Itching	3 (5)			3 (5)
Irritation	3 (5)			3 (5)
Burning	3 (5)			3 (5)
Hypopigmentation	2 (4)	2 (4)		
Shiny skin	1 (2)		1 (2)	
Secondary atopic dermatitis	1 (2)			1 (2)
Papules and pustules	1 (2)			1 (2)
Keratosis pilaris	1 (2)			1 (2)
Folliculitis	1 (2)		1 (2)	
Facial herpes simplex	1 (2)	1 (2)		
Acneiform eruption	1 (2)		1 (2)	
Ear infection	1 (2)		1 (2)	

*The number of individual adverse reactions reported does not necessarily reflect the number of individual subjects, since one subject could have multiple reports of an adverse reaction.

**End of Treatment

***Four Weeks Post Treatment

An open-label safety trial was conducted in 29 pediatric subjects 3 months to 2 years of age to assess the HPA axis by ACTH stimulation testing following use of fluocinolone acetonide topical oil twice daily for 4 weeks. The trial included 7 subjects ages 3 to 6 months, 7 subjects ages > 6 to 12 months, and 15 subjects ages > 12 months to 2 years. All subjects had moderate to severe atopic dermatitis with disease involvement on at least 20% body surface area (BSA). Eleven (11) subjects had baseline BSA involvement of 50% to 75% and 7 subjects had BSA involvement of greater than 75% *[see Use in Specific Populations (8.4)].* The most common adverse reactions reported in the study (≥2%) are shown in Table 2.

Table 2: Adverse Reactions in ≥ 2% of Pediatric Subjects 3 Months to 2 Years of Age with Moderate to Severe Atopic Dermatitis, Treated with Fluocinolone Acetonide Topical Oil (Body Oil), N=30*

Adverse Reaction	n (%)
Cough	6 (20)
Rhinorrhea	4 (13)
Pyrexia	3 (10)
Nasopharyngitis	2 (7)
Hypopigmentation	2 (7)
Abscess	1 (3)
Atopic Dermatitis	1 (3)
Eczema	1 (3)
Hyperpigmentation	1 (3)
Molluscum	1 (3)
Rash	1 (3)
Diarrhea	1 (3)
Otitis Media	1 (3)
URI	1 (3)
Vomiting	1 (3)

*Includes one subject who withdrew at Week 2

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of products containing topical corticosteroids. Because postmarketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- *Endocrine Disorders:* HPA axis suppression and Cushing's syndrome *[see Use in Specific Populations (8.4)]*
- *Eye Disorders:* glaucoma and cataracts *[see Warnings and Precautions (5.3)]*
- *Nervous System Disorders:* intracranial hypertension including bulging

fontanelles, headaches, and bilateral papilledema *[see Use in Specific Populations (8.4)]*

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from case reports, case series, and observational studies on fluocinolone acetonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Observational studies suggest maternal use of high to super-high potency topical steroids may be associated with an increased risk of low birthweight infants. Advise pregnant women to use fluocinolone acetonide topical oil on the smallest area of skin and for the shortest duration possible.

Corticosteroids can cause fetal malformations in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids cause fetal malformations after dermal application in laboratory animals.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of fluocinolone acetonide in breast milk or its effects on the breastfed infant or on milk production. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. To minimize potential exposure to the breastfed infant via breast milk, use fluocinolone acetonide topical oil on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply fluocinolone acetonide topical oil directly to the nipple and areola to avoid direct infant exposure *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.4)]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for fluocinolone acetonide topical oil and any potential adverse effects on the breastfed infant from fluocinolone acetonide topical oil or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of fluocinolone acetonide topical oil for the topical treatment of moderate to severe atopic dermatitis have been established in pediatric patients aged 3 months and older for up to 4 weeks.

Safety and effectiveness of fluocinolone acetonide topical oil in pediatric patients with

atopic dermatitis below the age of 3 months have not been established.

Systemic Adverse Reactions in Pediatric Patients

HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and subnormal response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk for systemic adverse reactions than are adults when treated with topical corticosteroids *[see Warnings and Precautions (5.1)].*

Evaluation in Peanut-Sensitive Pediatric Patients

A clinical trial was conducted to assess the safety of fluocinolone acetonide topical oil, which contains refined peanut oil, on pediatric subjects with known peanut allergies. The study enrolled 13 pediatric subjects with atopic dermatitis, 6 to 17 years of age. Of the 13 subjects, 9 were Radioallergosorbent Test (RAST) positive to peanuts and 4 had no peanut sensitivity (controls). The trial evaluated the subjects' responses to both prick test and patch test utilizing refined peanut oil, fluocinolone acetonide topical oil and histamine/saline controls. Subjects were also treated with fluocinolone acetonide topical oil twice daily for 7 days. Prick test and patch test results for all 13 patients were negative to fluocinolone acetonide topical oil and the refined peanut oil. One of the 9 peanut-sensitive patients experienced an exacerbation of atopic dermatitis after 5 days of fluocinolone acetonide topical oil.

Evaluation in Pediatric Patients 2 to 6 years old

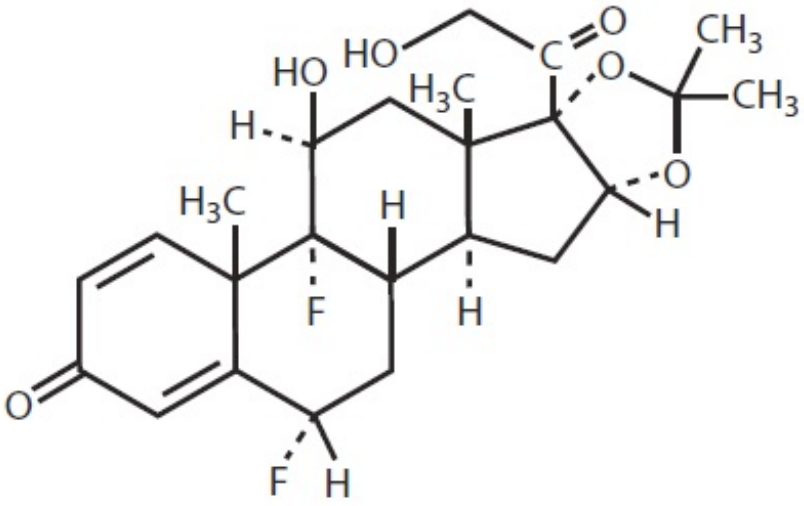
Use of fluocinolone acetonide topical oil in pediatric patients 2 to 6 years old is supported by open-label safety trials conducted in 33 pediatric subjects (20 subjects ages 2 to 6 years, 13 subjects ages 7 to 12 years) with moderate to severe stable atopic dermatitis. Baseline body surface area involvement was 50% to 75% in 15 subjects and greater than 75% in 18 subjects. Subjects were treated with fluocinolone acetonide topical oil twice daily for 4 weeks. Morning pre-stimulation cortisol and post-ACTH stimulation cortisol levels were obtained in each subject at the beginning of the trial and at the end of 4 weeks of treatment. At the end of treatment, 4 out of 18 subjects aged 2 to 5 years showed low pre-stimulation cortisol levels (3.2 to 6.6 µg/dL; normal: cortisol > 7µg/dL) but all had normal responses to 0.25 mg of ACTH stimulation (cortisol > 18 µg/dL) *[see Clinical Pharmacology (12.2)]*.

Evaluation in Pediatric Patients 3 months to 2 years old

Use of fluocinolone acetonide topical oil in pediatric patients 3 months to 2 years old is supported by an open-label safety trial conducted in 29 pediatric subjects (7 subjects ages 3 to 6 months, 7 subjects ages > 6 to 12 months, and 15 subjects ages > 12 months to 2 years) to assess the HPA axis by ACTH stimulation testing following use of fluocinolone acetonide topical oil twice daily for 4 weeks *[see Adverse Reactions (6.1)]*. Morning pre-stimulation and post-ACTH stimulation cortisol levels were obtained in each subject at the beginning of the trial and at the end of 4 weeks of treatment. All subjects had normal responses to 0.125 mg of ACTH stimulation (cortisol > 18 µg/dL) *[see Clinical Pharmacology (12.2)].*

11 DESCRIPTION

Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) contains fluocinolone acetonide [(6α, 11β, 16α)-6,9-difluoro-11,21-dihydroxy-16,17[(1-methylethylidene) bis(oxy)]-pregna-1,4-diene-3,20-dione, cyclic 16,17 acetal with acetone], a synthetic corticosteroid for topical dermatologic use. Chemically, fluocinolone acetonide is $C_{24}H_{30}F_2O_6$. It has the following structural formula:



Fluocinolone acetonide has a molecular weight of 452.50. It is a white crystalline powder that is odorless, stable in light, and melts at 270°C with decomposition; soluble in alcohol, acetone and methanol; slightly soluble in chloroform; insoluble in water.

Each gram of Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) contains approximately 0.11 mg of fluocinolone acetonide in a blend of oils, which contains isopropyl alcohol, isopropyl myristate, light mineral oil, oleth-2 and refined peanut oil.

Fluocinolone acetonide topical oil is formulated with 48% refined peanut oil. The bulk refined peanut oil, used in fluocinolone acetonide topical oil is heated just below 232°C (450°F) for at least 15 minutes.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the precise mechanism of action in atopic dermatitis is unknown.

12.2 Pharmacodynamics

Vasoconstrictor Assay

Fluocinolone acetonide topical oil is in the low to medium range of potency as compared

with other topical corticosteroids in vasoconstrictor studies. However, similar blanching scores do not necessarily imply therapeutic equivalence.

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

HPA axis suppression was evaluated in 29 pediatric subjects 3 months to 2 years old (7 subjects ages 3 to 6 months, 7

subjects ages > 6 to 12 months, and 15 subjects ages > 12 months to 2 years) and 33 pediatric subjects 2 years to 12 years old (20 subjects ages 2 to 6 years, 13 subjects ages 7 to 12 years) with moderate to severe atopic dermatitis. Subjects were treated with fluocinolone acetonide topical oil twice daily for 4 weeks. Morning pre-stimulation and post-ACTH stimulation cortisol levels were obtained in each subject at the beginning of the trial and at the end of 4 weeks of treatment. In subjects 3 months to 2 years old, all subjects had normal responses to 0.125 mg of ACTH stimulation (cortisol > 18 µg/dL). In subjects 2 to 12 years old, 4 out of 18 subjects 2 to 5 years old showed low pre-stimulation cortisol levels (3.2 to 6.6 µg/dL; normal: cortisol > 7µg/dL) but all had normal responses to 0.25 mg of ACTH stimulation (cortisol > 18 µg/dL) at the end of treatment *[see Warnings and Precautions (5.1) and Use in Specific Populations (8.4)]*.

12.3 Pharmacokinetics

Topical corticosteroids can be absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the product formulation and the integrity of the epidermal barrier. Occlusion, inflammation and/or other disease processes in the skin may increase percutaneous absorption.

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids may be necessary due to the fact that circulating levels are often below the level of detection. Once absorbed through the skin, topical corticosteroids are metabolized primarily in the liver, and are then excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, mutagenesis, impairment of fertility

No carcinogenicity, genotoxicity, or fertility studies were conducted with fluocinolone acetonide topical oil. However, some corticosteroids are genotoxic in various genotoxicity tests (i.e., the *in vitro* human peripheral blood lymphocyte chromosome aberration assay with metabolic activation, the *in vivo* mouse bone marrow micronucleus assay, the Chinese hamster micronucleus test, and the *in vitro* mouse lymphoma gene mutation assay).

16 HOW SUPPLIED / STORAGE AND HANDLING

Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil) (NDC 45802-**887**-26) is supplied in bottles containing 4 fluid ounces.

Storage: Keep tightly closed. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) *[see USP Controlled Room Temperature].*

Administration Instructions

Advise patients that fluocinolone acetonide topical oil is for topical use only *[see Dosage and Administration (2.1)]*.

Advise patients to not to apply fluocinolone acetonide topical oil under occlusion unless directed by their healthcare provider. Instruct patients not to apply fluocinolone acetonide topical oil to the diaper area as diapers or plastic pants may constitute occlusive use *[see Dosage and Administration (2.1)]*.

Advise patients to avoid use of fluocinolone acetonide topical oil on the face, axillae, or groin unless directed by their healthcare provider *[see Dosage and Administration (2.1)]*.

Advise patients to discontinue therapy when control of disease is achieved. Instruct patients to contact their healthcare provider if no improvement is seen within 2 weeks *[see Dosage and Administration (2.1)]*.

Endocrine System Adverse Reactions

Instruct patients not to use other corticosteroid-containing products while using fluocinolone acetonide topical oil without first consulting their healthcare provider *[see Warnings and Precautions (5.1)]*.

Ophthalmic Adverse Reactions

Advise patients to avoid contact with the eyes and in case of contact, wash eyes liberally with water. Instruct patients to tell their healthcare provider if they develop any visual symptoms *[see Warnings and Precautions (5.3)]*.

Pregnancy and Lactation

Advise patients to use fluocinolone acetonide topical oil on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise patients that are breastfeeding not to apply fluocinolone acetonide topical oil directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.1 and 8.2)].*

Manufactured by Padagis®,

Yeruham, Israel

8R726 RC F8

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 45802-887-26

Rx Only

Fluocinolone Acetonide Topical Oil, 0.01% (Body Oil)

FOR TOPICAL USE ONLY

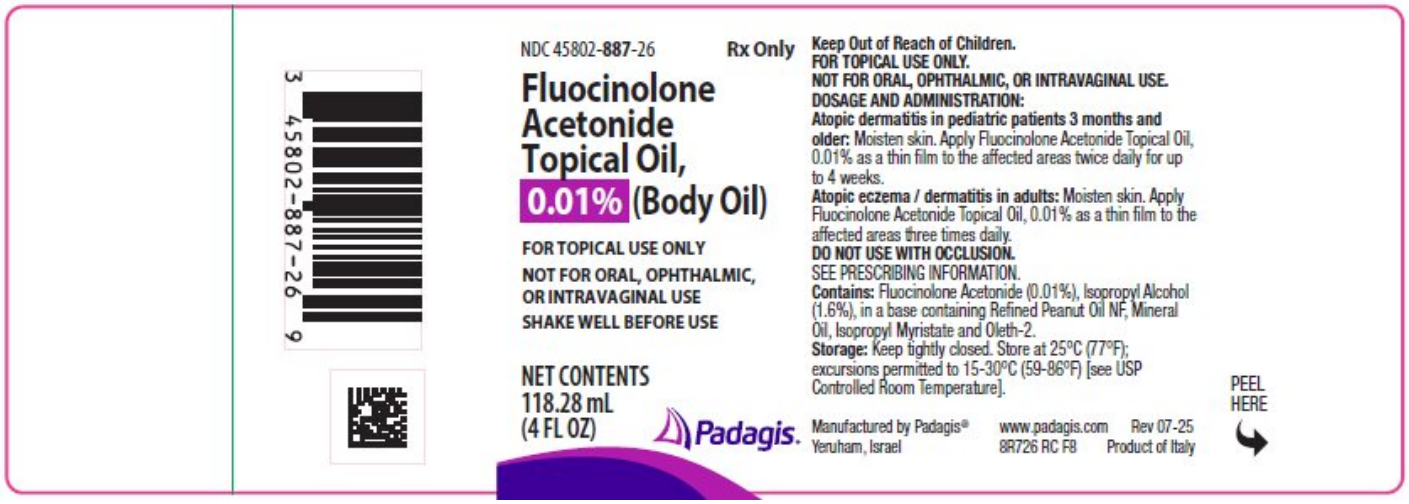
NOT FOR ORAL, OPHTHALMIC, OR INTRAVAGINAL USE

SHAKE WELL BEFORE USE

NET CONTENTS

118.28 mL

(4 FL OZ)



FLUOCINOLONE ACETONIDE

fluocinolone acetonide oil

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45802-887
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUOCINOLONE ACETONIDE (UNII: 0CD5FD6S2M) (FLUOCINOLONE ACETONIDE - UNII:0CD5FD6S2M)	FLUOCINOLONE ACETONIDE	0.01 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
OLETH-2 (UNII: 7L6R1SQ6M0)	

Product Characteristics			
Color	YELLOW (PALE YELLOW)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-887-26	118.28 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202847	06/14/2017	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 7/2025 Padagis Israel Pharmaceuticals Ltd