

DESOXIMETASONE- desoximetasone spray

Padagis Israel Pharmaceuticals Ltd

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DESOXIMETASONE TOPICAL SPRAY safely and effectively. See full prescribing information for DESOXIMETASONE TOPICAL SPRAY.

DESOXIMETASONE topical spray

Initial U.S. Approval: 1977

INDICATIONS AND USAGE

Desoximetasone topical spray is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older (1).

DOSAGE AND ADMINISTRATION

- Apply a thin film to the affected skin areas twice daily. Rub in gently. (2)
- Discontinue treatment when control is achieved. (2)
- Treatment beyond 4 weeks is not recommended. (2)
- Do not use if atrophy is present at the treatment site. (2)
- Do not use with occlusive dressings, unless directed by the physician. (2)
- Avoid use on the face, axilla or groin. (2)
- Not for oral, ophthalmic, or intravaginal use. (2)

DOSAGE FORMS AND STRENGTHS

Spray, 0.25% w/w (3)

CONTRAINDICATIONS

None (4)

WARNINGS AND PRECAUTIONS

- *Effect on Endocrine System:* Desoximetasone topical spray can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during or after treatment. (5.1)
- Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can result from systemic absorption of topical corticosteroids. (5.1)
- Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. (5.1)
- Modify use if HPA axis suppression develops. (5.1)
- High potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age may predispose patients to HPA axis suppression. (5.1)
- Pediatric patients may be more susceptible to systemic toxicity when treated with topical corticosteroids. Safety and effectiveness have not been established in pediatric patients and use in pediatric patients is not recommended. (5.1, 8.4)
- *Ophthalmic Adverse Reactions:* Topical corticosteroid products may increase the risk of cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist. (5.3).
- *Flammability:* Desoximetasone topical spray is flammable; keep away from heat or flame. (5.6)

ADVERSE REACTIONS

The most common adverse reactions ($\geq 1\%$) are application site dryness, application site irritation and application site pruritus. (6.1)

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 and FDA-approved patient labeling.

Revised: 8/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Effect on Endocrine System
- 5.2 Local Adverse Reactions with Topical Corticosteroids
- 5.3 Ophthalmic Adverse Reactions
- 5.4 Allergic Contact Dermatitis with Topical Corticosteroids
- 5.5 Concomitant Skin Infections
- 5.6 Flammability

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.2 Lactation
- 8.4 Pediatric Use
- 8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

- 16.1 How Supplied/Storage
- 16.2 Instructions for the Pharmacist

17 PATIENT COUNSELING INFORMATION

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Desoximetasone topical spray is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

2 DOSAGE AND ADMINISTRATION

Apply desoximetasone topical spray as a thin film to the affected skin areas twice daily. Rub in gently.

Do not bandage or otherwise cover or wrap the treated skin unless directed by the physician.

Discontinue treatment when control is achieved.

Treatment beyond 4 weeks is not recommended.

Do not use if atrophy is present at the treatment site.

Avoid use on the face, axilla or groin.

Desoximetasone topical spray is for external use only. It is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Topical Spray, 0.25%. Each gram of desoximetasone topical spray contains 2.5 mg of desoximetasone in a clear, colorless liquid.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Effect on Endocrine System

Desoximetasone topical spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

In a study including 21 evaluable subjects 18 years of age or older with moderate to severe plaque psoriasis, adrenal suppression was identified in 1 out of 12 subjects having involvement of 10 to 15% of body surface area (BSA) and 2 out of 9 subjects having involvement of >15% of BSA after treatment with desoximetasone topical spray twice a day for 28 days [see *Clinical Pharmacology (12.2)*].

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency steroids, larger treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.

Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.

Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids. Use in patients under 18 years of age is not recommended due to numerically high rates of HPA axis suppression (the safety and effectiveness of desoximetasone topical spray have not been established in pediatric patients) [see *Use in Specific Populations (8.4)* and *Clinical Pharmacology (12.2)*].

5.2 Local Adverse Reactions with Topical Corticosteroids

Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

5.3 Ophthalmic Adverse Reactions

Use of topical corticosteroids, including desoximetasone topical spray, may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported with the postmarketing use of topical corticosteroid products [see *Adverse Reactions (6.2)*]. Avoid contact of desoximetasone topical spray with eyes. Desoximetasone topical spray may cause eye irritation. Advise patients to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

5.4 Allergic Contact Dermatitis with Topical Corticosteroids

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

Concomitant skin infections should be treated with an appropriate antimicrobial agent. If the infection persists, desoximetasone topical spray should be discontinued until the infection has been adequately treated.

5.6 Flammability

Desoximetasone topical spray is flammable; keep away from heat or flame.

6 ADVERSE REACTIONS

6.1 Clinical Trials 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.

In randomized, multicenter, prospective vehicle-controlled clinical trials, subjects with moderate to severe plaque psoriasis of the body applied desoximetasone topical spray or vehicle spray twice daily for 4 weeks. A total of 149 subjects applied desoximetasone topical spray.

Adverse reactions that occurred in $\geq 1\%$ of subjects treated with desoximetasone topical spray are presented in Table 1.

Table 1. Number (%) of Subjects with Adverse Reactions Occurring in $\geq 1\%$

	Desoximetasone Topical Spray, 0.25% <i>b.i.d.</i> (N = 149)	Vehicle spray <i>b.i.d.</i> (N = 135)
Number of Subjects with Adverse Reactions	13 (8.7%)	18 (13.3%)
Application site dryness	4 (2.7%)	7 (5.2%)
Application site irritation	4 (2.7%)	5 (3.7%)
Application site pruritus	3 (2.0%)	5 (3.7%)

Another less common adverse reaction ($<1\%$ but $>0.1\%$) was folliculitis.

6.2 Postmarketing Experience

Because 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.

Postmarketing reports for local adverse reactions to topical corticosteroids included atrophy, striae, telangiectasias, itching, dryness, hypopigmentation, perioral dermatitis, secondary infection, and miliaria.

Ophthalmic adverse reactions of cataracts, glaucoma, and increased intraocular pressure have been reported during use of topical corticosteroids.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on desoximetasone use in pregnant women to evaluate for 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, including desoximetasone topical spray, may be associated with an increased risk of low birthweight infants (*see Data*). Advise pregnant woman that desoximetasone topical spray may increase the potential risk of low birth weight infants and to use desoximetasone topical spray on the smallest area of skin and for the shortest duration possible. Desoximetasone has been shown to cause malformations and be embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration at doses 3 to 30 times the human dose of desoximetasone

topical spray based on a body surface area comparison.

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.

Data

Human Data

Available observational studies in pregnant women did not identify a drug-associated risk of major birth defects, preterm delivery, or fetal mortality with the use of topical corticosteroids of any potency. However, when the dispensed amount of high to super-high potency topical corticosteroids exceeded 300g during the entire pregnancy, maternal use was associated with an increased risk of low birth weight in infants.

8.2 Lactation

Risk Summary

There is no information on the presence of topically administered desoximetasone in human milk, the effects on the breastfed infant, or the effects 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. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for desoximetasone topical spray and any potential adverse effects on the breastfed infant from desoximetasone topical spray or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use desoximetasone topical spray on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply desoximetasone topical spray directly to the nipple and areola to avoid direct infant exposure [see *Warnings and Precautions (5.1) and Use in Specific Populations (8.4)*].

8.4 Pediatric Use

The safety and effectiveness of desoximetasone topical spray have not been established in pediatric patients for the treatment of plaque psoriasis. Desoximetasone topical spray is not recommended for use in patients less than 18 years of age due to the high incidence of HPA axis suppression observed [see *Warnings and Precautions (5.1)*].

Hypothalamic-Pituitary Adrenal (HPA) Axis Suppression

The HPA axis suppression potential of desoximetasone topical spray was assessed in an open-label, sequential cohort, safety trial in 129 subjects 2 years to less than 18 years of age with moderate to severe plaque psoriasis defined as a Physician Global Assessment (PGA) score of ≥ 3 with involvement of at least 10% of their body surface area (excluding the face and scalp). In total, 100 pediatric subjects were evaluated for HPA axis function via cosyntropin stimulation testing at baseline and following 4 weeks of twice daily application of desoximetasone topical spray. Overall, 36% of pediatric

subjects 2 years to less than 18 years of age demonstrated HPA axis suppression defined as a serum cortisol level \leq 18 mcg/dL 30-minutes post cosyntropin stimulation. The proportion of subjects demonstrating HPA axis suppression was 35.0% in Cohort 1 (12 years to less than 18 years of age) and 43.3% in Cohort 2 (6 years to less than 12 years of age). Trial enrollment in the youngest cohort (2 years to less than 6 years of age) was discontinued early due to high incidence of HPA axis suppression observed in the two oldest cohorts (6 years to less than 18 years of age) [see *Clinical Pharmacology* (12.2)].

Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse reactions including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

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

8.5 Geriatric Use

Clinical studies of desoximetasone topical spray did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE

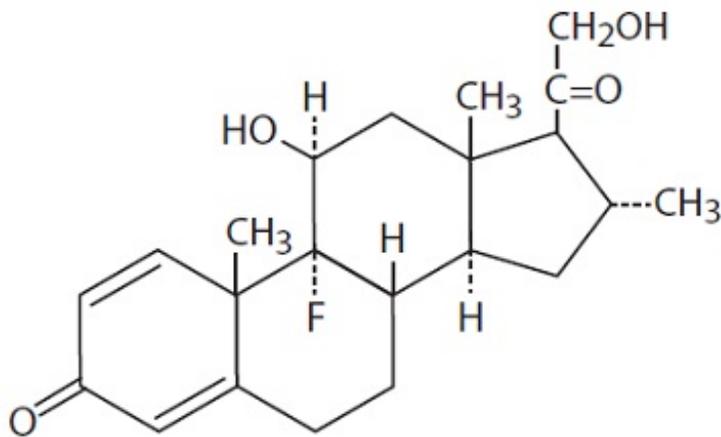
Desoximetasone topical spray can be absorbed in sufficient amounts to produce systemic effects [see *Warnings and Precautions* (5.1)].

11 DESCRIPTION

Desoximetasone Topical Spray, 0.25% for dermatologic use contains desoximetasone as the active ingredient.

Desoximetasone is a corticosteroid with the chemical name of pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-, (11 β ,16 α)-. Desoximetasone has the molecular formula of C₂₂H₂₉FO₄ and a molecular weight of 376.47. The CAS Registry Number is 382-67-2.

The structural formula is:



Each gram of desoximetasone topical spray contains 2.5 mg of desoximetasone in a clear, colorless liquid with the following inactive ingredients: glyceryl oleate, isopropyl alcohol (23.4%), isopropyl myristate, L-menthol, and mineral oil. Desoximetasone topical spray is co-packaged with a manual spray pump for installation by the pharmacist prior to dispensing to patients.

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 psoriasis is unknown.

12.2 Pharmacodynamics

Vasoconstrictor Assay

Vasoconstrictor studies performed with desoximetasone topical spray in healthy subjects indicate that it is in the high to super-high range of potency as compared with other topical corticosteroids.

Hypothalamic-Pituitary Adrenal (HPA) Axis Suppression

The potential for hypothalamic-pituitary-adrenal (HPA) axis suppression was evaluated in two trials. Desoximetasone topical spray was applied twice a day for 28 days and HPA axis suppression was defined as serum cortisol level ≤ 18 mcg/dL 30-min post cosyntropin stimulation.

In the first trial, out of 24 adult subjects with moderate to severe plaque psoriasis, 21 subjects had evaluable serum cortisol levels. The proportion of subjects demonstrating HPA axis suppression was 8.3% (1 out of 12) in subjects having psoriasis involvement of 10-15% of body surface area (BSA), and 22.2% (2 out of 9) in subjects having psoriasis involvement of >15% of their BSA. In the 2 subjects with available follow-up values, suppression reversed 28 days after the end of treatment.

In another trial, the HPA axis suppression was evaluated in 106 pediatric subjects with moderate to severe plaque psoriasis. One hundred subjects had evaluable serum cortisol levels. The proportion of subjects demonstrating HPA axis suppression was

35.0% (21 out of 60) in Cohort 1 (12 years to less than 18 years of age, with a mean baseline BSA involvement of 16%), and 43.3% (13 out of 30) in Cohort 2 (6 years to less than 12 years of age, with a mean baseline BSA involvement of 19%). Trial enrollment in the youngest cohort (2 years to less than 6 years of age) was discontinued early due to high incidence of HPA axis suppression observed in the two oldest cohorts (6 years to less than 18 years of age).

The overall HPA axis suppression rate was 36% in pediatric subjects 2 years to less than 18 years of age. Due to high incidence of HPA axis suppression observed from this trial, desoximetasone topical spray is not recommended for use in pediatric patients less than 18 years of age [see *Use in Specific Populations (8.4)*].

12.3 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. 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.

Plasma concentrations of desoximetasone were measured at two single random time points in the HPA axis suppression trial in 24 adult subjects with psoriasis [see *Clinical Pharmacology (12.2)*]. The mean (% Coefficient of Variation) concentration of desoximetasone was 449 pg/mL (86%) at Day 14 and 678 pg/mL (135%) at Day 28. The concentration time profile following application of desoximetasone topical spray is not known.

In the pediatric HPA axis suppression trial, plasma concentrations of desoximetasone were measured in a subset of subjects in Cohorts 1 and 2 [see *Clinical Pharmacology (12.2)*]. High inter subject variability in plasma concentrations was observed in both cohorts. The mean (% Coefficient of Variation) maximum concentration on Day 29 was 1881 pg/mL (127%) in Cohort 1 (n=11) and 1116 pg/mL (94%) in Cohort 2 (n=8).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of desoximetasone topical spray.

In a 13-week repeat-dose toxicity study in rats, topical administration of desoximetasone spray at concentrations of 0.001, 0.005 and 0.02% BID (which corresponds to dose levels of 0.01, 0.05, or 0.2 mg/kg/dose BID, respectively) resulted in a toxicity profile consistent with long-term exposure to corticosteroids, including adrenal atrophy and histopathological changes in several organ systems indicative of

severe immune suppression. A no observable adverse effect level (NOAEL) could not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk for carcinogenesis.

Desoximetasone revealed no evidence of mutagenic or clastogenic potential based on the results of two *in vitro* genotoxicity tests (Ames assay and Chinese hamster ovary cell chromosome aberration assay) and one *in vivo* genotoxicity test (mouse bone marrow micronucleus assay).

No evidence of impairment of male or female fertility was observed at subcutaneous desoximetasone doses up to 0.1 mg/kg/day (0.6 mg/m²/day) in Sprague-Dawley rats.

14 CLINICAL STUDIES

Two multi-center, randomized, double-blind, vehicle-controlled clinical trials were conducted in 239 subjects aged 18 years and older with moderate to severe plaque psoriasis of the body. In both trials, randomized subjects applied desoximetasone topical spray or vehicle spray to the affected areas twice daily for 4 weeks. Enrolled subjects had a minimum body surface area of involvement of 10%, and a Physician's Global Assessment score (PGA) of 3 (moderate) or 4 (severe).

Efficacy was assessed at Week 4 as the proportion of subjects who were considered a Clinical Success ("clear" (0) or "almost clear" (1) according to the PGA scale). Table 2 presents the efficacy results.

Table 2. Number of Subjects (%) with Clinical Success (scored as clear or almost clear) at Week 4.

Parameter	Trial 1		Trial 2	
	Desoximetasone Topical Spray N = 59	Vehicle N = 60	Desoximetasone Topical Spray N = 60	Vehicle N = 60
Clinical Success	18 (30.5%)	3 (5.0%)	32 (53.3%)	11 (18.3%)

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied/Storage

Desoximetasone Topical Spray, 0.25% is a clear colorless liquid supplied in white, opaque bottles with white, opaque screw caps in the following size:

- 100 mL (NDC 45802-**807**-98)

Store at controlled room temperature between 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

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

Each unit is co-packaged with a manual spray pump for installation by the pharmacist.

16.2 Instructions for the Pharmacist

1. Remove the spray pump from the wrapper
2. Remove and discard the cap from the bottle
3. Keeping the bottle vertical, puncture seal, insert the spray pump into the bottle and turn clockwise until well-fastened
4. Dispense the bottle with the spray pump inserted
5. Label the bottle with “discard the product 30 days after dispensing”

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information and Instructions for Use) Inform patients of the following:

- Use this medication as directed by the physician. Do not use this medication for any disorder other than that for which it was prescribed.
- Desoximetasone topical spray is for external use only.
- Avoid contact with eyes and use on the face, axilla or groin.
- To minimize the risk of adverse reactions:
 - o do not bandage or otherwise cover or wrap the treated skin so as to be occlusive.
 - o discontinue therapy when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
 - o do not use other corticosteroid-containing products with desoximetasone topical spray without first consulting with the physician.
- Advise patients that desoximetasone topical spray may require periodic evaluation for HPA axis suppression. Topical corticosteroids may have other endocrine effects. *[see Warnings and Precautions (5.1)]*.
- Advise women to use desoximetasone topical spray on the smallest area of skin and for the shortest duration possible while pregnant or breastfeeding. Advise breastfeeding woman not to apply desoximetasone topical spray directly to the nipple and areola to avoid direct infant exposure *[see Use in Specific Populations (8.1 and 8.2)]*.
- Report any signs of local or systemic adverse reactions including any visual symptoms to the physician.
- This medication is flammable; avoid heat, flame, or smoking when applying this product.
- Discard this product 30 days after dispensed by pharmacist.

Manufactured by Padagis®

Yeruham, Israel

www.padagis.com

Rev 08-23

7Y200 RC PH4

Patient Information

PATIENT INFORMATION

Desoximetasone (des ox" i met' a sone) Topical Spray

Important information: Desoximetasone topical spray is for use on skin (topical) only.

Do not get desoximetasone topical spray near or in your mouth, eyes or vagina.

What is desoximetasone topical spray?

Desoximetasone topical spray is a prescription corticosteroid medicine used to treat plaque psoriasis of the body in people 18 years of age and older.

It is not known if desoximetasone topical spray is safe and effective in children under 18 years of age. Desoximetasone topical spray is not recommended for use in children under 18 years of age.

Before you use desoximetasone topical spray, tell your doctor about all of your medical conditions, including if you:

- have had irritation or other skin reaction to a steroid medicine in the past.
- have a skin infection. You may need medicine to treat the skin infection before you use desoximetasone topical spray.
- have thinning of the skin (atrophy) at the treatment site
- have adrenal gland problems
- have diabetes
- liver problems
- are pregnant or plan to become pregnant. It is not known if desoximetasone topical spray will harm your unborn baby. Desoximetasone topical spray may increase your chance of having a low birthweight baby. If you use desoximetasone topical spray during pregnancy, use desoximetasone topical spray on the smallest area of the skin and for the shortest time needed.
- are breastfeeding or plan to breastfeed. It is not known if desoximetasone passes into your breast milk. If you use desoximetasone topical spray and breastfeed, use desoximetasone topical spray on the smallest area of the skin and for the shortest time needed. Do not apply desoximetasone topical spray directly to the nipple and areola to avoid contact with your baby.

have a skin infection. You may need medicine to treat the skin infection before you use desoximetasone topical spray.

have thinning of the skin (atrophy) at the treatment site

have adrenal gland problems

have diabetes

liver problems

are pregnant or plan to become pregnant. It is not known if desoximetasone topical spray will harm your unborn baby. Desoximetasone topical spray may increase your chance of having a low birthweight baby. If you use desoximetasone topical spray during pregnancy, use desoximetasone topical spray on the smallest area of the skin and for the shortest time needed.

are breastfeeding or plan to breastfeed. It is not known if desoximetasone passes into your breast milk. If you use desoximetasone topical spray and breastfeed, use desoximetasone topical spray on the smallest area of the skin and for the shortest time needed. Do not apply desoximetasone topical spray directly to the nipple and areola to

avoid contact with your baby.

Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your doctor if you take other corticosteroid medicines by mouth or use other products on your skin that contain corticosteroids. Do not use other products containing a corticosteroid medicine while using desoximetasone topical spray without talking to your doctor first.

What should I avoid while using desoximetasone topical spray?

Desoximetasone topical spray is flammable. Avoid heat, flames or smoking while applying desoximetasone topical spray to your skin.

How should I use desoximetasone topical spray?

See the “Instructions for Use” for detailed information about the right way to apply desoximetasone topical spray.

- Use desoximetasone topical spray exactly as your doctor tells you to use it.
- Your doctor should tell you how much desoximetasone topical spray to use and where to use it.
- Apply desoximetasone topical spray to the affected skin areas 2 times a day and rub it in gently.
- Do not bandage, cover, or wrap the treated skin area, unless your doctor tells you to.
- Use desoximetasone topical spray for the shortest amount of time needed to treat your plaque psoriasis. Tell your doctor if your skin condition is not getting better after 4 weeks of using desoximetasone topical spray. You should not use desoximetasone topical spray for longer than 4 weeks.
- Do not use desoximetasone topical spray on your face, armpits or groin.
- Do not use desoximetasone topical spray if you have thinning of your skin (atrophy) at the treatment site.
- Wash your hands after applying desoximetasone topical spray.

Your doctor should tell you how much desoximetasone topical spray to use and where to use it.

Apply desoximetasone topical spray to the affected skin areas 2 times a day and rub it in gently.

Do not bandage, cover, or wrap the treated skin area, unless your doctor tells you to.

Use desoximetasone topical spray for the shortest amount of time needed to treat your plaque psoriasis. Tell your doctor if your skin condition is not getting better after 4 weeks of using desoximetasone topical spray. You should not use desoximetasone topical spray for longer than 4 weeks.

Do not use desoximetasone topical spray on your face, armpits or groin.

Do not use desoximetasone topical spray if you have thinning of your skin (atrophy) at the treatment site.

Wash your hands after applying desoximetasone topical spray.

What are the possible side effects of desoximetasone topical spray?

Desoximetasone topical spray may cause serious side effects, including:

- **Symptoms of a disorder where the adrenal gland does not make enough of certain hormones (adrenal insufficiency) during treatment or after stopping treatment with desoximetasone topical spray.** Your doctor may do blood tests to check for adrenal gland problems.
- **Cushing’s syndrome**, a condition that happens when your body is exposed to

large amounts of the hormone cortisol. Your doctor may do tests to check for this.

- **High blood sugar (hyperglycemia) or diabetes mellitus that has not been diagnosed can happen when treated with desoximetasone topical spray.** Your doctor may do tests to check for this.
- **Skin reactions at the treated skin site.** Tell your doctor if you get any skin reactions or skin infections.
- **Eye problems.** Using desoximetasone topical spray may increase your chance of getting cataracts and glaucoma. Do not get desoximetasone topical spray in your eyes because it may cause eye irritation. Tell your doctor if you have blurred vision or other vision problems during treatment with desoximetasone topical spray.

Cushing's syndrome, a condition that happens when your body is exposed to large amounts of the hormone cortisol. Your doctor may do tests to check for this.

High blood sugar (hyperglycemia) or diabetes mellitus that has not been diagnosed can happen when treated with desoximetasone topical spray. Your doctor may do tests to check for this.

Skin reactions at the treated skin site. Tell your doctor if you get any skin reactions or skin infections.

Eye problems. Using desoximetasone topical spray may increase your chance of getting cataracts and glaucoma. Do not get desoximetasone topical spray in your eyes because it may cause eye irritation. Tell your doctor if you have blurred vision or other vision problems during treatment with desoximetasone topical spray.

The most common side effects of desoximetasone topical spray include dryness, irritation and itching of skin at the treated site.

These are not all the possible side effects of desoximetasone topical spray.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store desoximetasone topical spray?

- Store desoximetasone topical spray at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) unused desoximetasone topical spray after 30 days.

Throw away (discard) unused desoximetasone topical spray after 30 days.

Keep desoximetasone topical spray and all medicines out of the reach of children.

General information about the safe and effective use of desoximetasone topical spray.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use desoximetasone topical spray for a condition for which it was not prescribed. Do not give desoximetasone topical spray to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or doctor for information about desoximetasone topical spray that is written for health professionals.

What are the ingredients in desoximetasone topical spray?

Active ingredient: desoximetasone

Inactive ingredients: glyceryl oleate, isopropyl alcohol, isopropyl myristate, L-menthol, and mineral oil

Manufactured by Padagis®

Yeruham, Israel

This Patient Information has been approved by the U.S. Food and Drug Administration.

Instructions for Use

Desoximetasone (des ox" i met' a sone) Topical Spray

Important information:

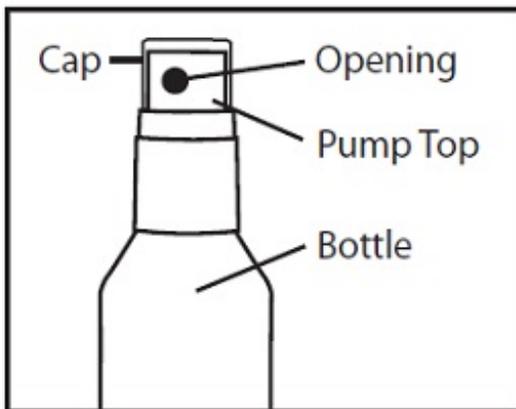
Desoximetasone topical spray is for use on skin (topical) only.

Do not get desoximetasone topical spray near or in your mouth, eyes or vagina.

Read the Instructions for Use before you start using desoximetasone topical spray and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

Parts of desoximetasone topical spray bottle (See Figure A).

Figure A

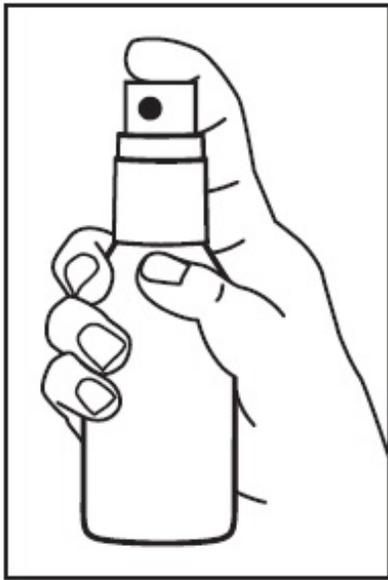


How to apply desoximetasone topical spray:

Step 1: Remove the cap from the pump top.

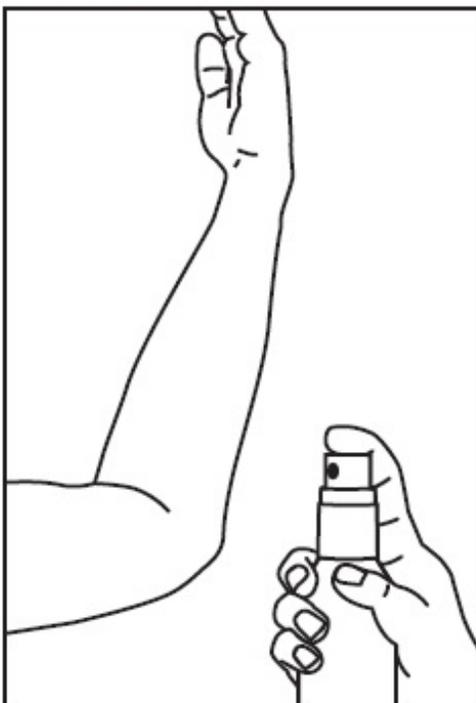
Step 2: Hold the bottle in an upright position while pointing the opening of the pump top in the direction of the affected area. To spray, push down on the pump top. Apply desoximetasone topical spray to the affected area as instructed by your doctor. **(See Figure B).**

Figure B



Step 3: Spray only enough desoximetasone topical spray to cover the affected area, for example, the elbow (**See Figure C**). Rub in desoximetasone topical spray gently to the affected area.

Figure C

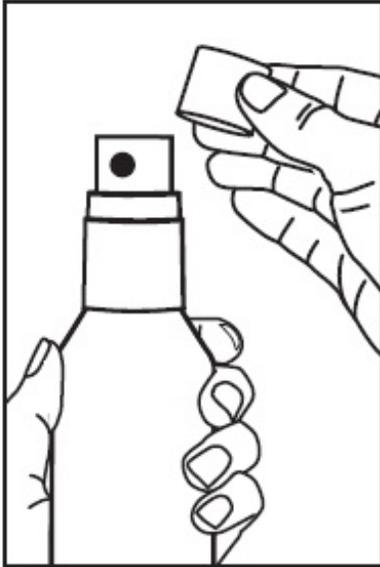


Repeat Steps 2 and 3 to apply desoximetasone topical spray to other affected areas as instructed by your doctor.

Step 4: After applying desoximetasone topical spray, place the cap back onto the pump

top (See Figure D).

Figure D



How should I store desoximetasone topical spray?

- Store desoximetasone topical spray at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) unused desoximetasone topical spray 30 days after it has been opened.
- Desoximetasone topical spray is flammable. Keep away from heat, flames or smoke.

Keep desoximetasone topical spray and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by Padagis®
Yeruham, Israel

www.padagis.com

Rev 08-23
7Y200 RC PH4

Package/Label Display Panel - 100 mL Carton

Rx Only

NDC 45802-807-98

Desoximetasone Topical Spray, 0.25%

For Topical Use Only

Not For Oral, Ophthalmic, or Intravaginal Use

100 mL



The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
 Lot [insert product's lot number]
 Exp [insert product's expiration date]

DESOXIMETASONE

desoximetasone spray

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:45802-807
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESOXIMETASONE (UNII: 4E07GXB7AU) (DESOXIMETASONE - UNII:4E07GXB7AU)	DESOXIMETASONE	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL OLEATE (UNII: 4PC054V79P)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-807-98	1 in 1 CARTON	12/06/2018	
1		100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206441	12/06/2018	

Revised: 8/2023

Padagis Israel Pharmaceuticals Ltd