PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

[Pr]DESOXI

Desoximetasone Cream, USP
Cream, 0.05% w/w and 0.25% w/w, Topical

Desoximetasone Gel, USP
Gel, 0.05% w/w, Topical

Topical Corticosteroid

TaroPharma, A Division of
Taro Pharmaceuticals Inc.
130 East Drive
Brampton, Ontario, Canada
L6T 1C1

Date of Initial Authorization:
November 16, 1998

Date of Revision:
September 12, 2023

Submission Control Number: 267843

RECENT MAJOR LABEL CHANGES

1 INDICATIONS, 1.1 Pediatrics	09/2023
1 INDICATIONS, 1.2 Geriatrics	09/2023
2 CONTRAINDICATIONS	09/2023
4 DOSAGE AND ADMINISTRATION, 4.1 Dosing Considerations	09/2023
7 WARNINGS AND PRECAUTIONS	09/2023
7 WARNINGS AND PRECAUTIONS, 7.1.3 Pediatrics	09/2023

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

DESOXI is indicated for the relief of acute or chronic corticosteroid-responsive dermatoses.

1.1 Pediatrics (> 18 years old)

DESOXI is indicated for use in pediatric patients (see 4.1 Dosing Considerations and 7.1.3 Pediatrics)

1.2 Geriatrics (≤ 65 years old)

Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness.

2 CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the 6 DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Product Monograph.
- Topical corticosteroids are contraindicated in untreated bacterial, tubercular, fungal and most viral lesions of the skin (including herpes simplex, vaccinia and varicella) and in those patients with a history of hypersensitivity to any of the components of the preparation.
- DESOXI is not for ophthalmic use.
- Topical corticosteroids when used over large areas, at high doses for prolonged period or under an airtight dressing are more likely to be absorbed into the bloodstream and cause side effects. Apply only enough to cover the affected areas. DESOXI should not be applied over large areas unless advised by your doctor.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- Topical corticosteroids when used over large areas, at high doses for prolonged period or under an airtight dressing are more likely to be absorbed into the bloodstream and cause side effects. Apply only enough to cover the affected

areas. DESOXI should not be applied over large areas unless advised by the healthcare professional.

- There are risks associated with sudden discontinuation after prolonged use of corticosteroids such as exacerbation or recurrence of the underlying disease, adrenocortical insufficiency or steroid withdrawal syndrome. DESOXI should not be suddenly discontinued unless advised by the healthcare professional (see 7 WARNINGS AND PRECAUTIONS, Endocrine and Metabolism).

- DESOXI has been shown to be safe and effective in children and is indicated in this population. However, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. 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.

4.2 Recommended Dose and Dosage Adjustment

Apply a thin film of DESOXI to the affected skin areas twice daily. Rub in gently.

5 OVERDOSAGE

Toxic effects due to prolonged percutaneous absorption of large amounts of corticosteroids may include: reversible suppression of adrenal function, skin striae, ecchymoses discoloration or atrophy, acneiform eruptions, hirsutism, infection. Prolonged systemic corticosteroids action may cause hypertension, peptic ulceration, hypokalemia, muscle weakness and wastage and subcapsular cataracts.

Treatment should include symptomatic therapy and discontinuation of corticosteroid administration. In chronically affected patients, a gradual discontinuation may prevent the development of steroid withdrawal symptoms.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1: Dosage Forms, Strengths, Composition and Packaging

Route of Administration	**Dosage Form / Strength/ Composition**	**Non-Medicinal Ingredients**
Topical	Cream 0.25% w/w; Cream 0.05% w/w	Cetostearyl alcohol, isopropyl myristate, lactic acid (if necessary for pH adjustment of the 0.05% cream), lanolin alcohol, mineral oil, sodium edetate (0.05% strength only),

		white petrolatum and water.
	Gel 0.05% w/w	Carbomer 940 (Carbopol® 980), disodium EDTA, docusate sodium, isopropyl myristate, SD ethanol (containing denatonium benzoate, or sucrose ocataacetate as a denaturant), trolamine and water.

DESOXI (desoximetasone) cream is available in strengths of 0.05% (0.5 mg/g) and 0.25% (2.5 mg/g). It is supplied in tubes of 20 g and 60 g.

DESOXI (desoximetasone) gel is available in 0.05% (0.5 mg/g) strength. It is supplied in tubes of 20 g and 60g.

7 WARNINGS AND PRECAUTIONS

General

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

Infection

If local infection exists, suitable concomitant antimicrobial or antifungal therapy should be administered as primary therapy. If it is considered necessary, the topical corticosteroid may be used as an adjunct to control inflammation, erythema and itching. If a favourable response does not occur promptly, application of the corticosteroid should be discontinued until the infection is adequately controlled.

Endocrine and Metabolism

Hyperglycemia has been reported as a systemic adverse effects of desoximetasone administration. Adrenal suppression has been shown to occur with prolonged use of large doses of topical corticosteroids, particularly under occlusion due to increased percutaneous absorption.

The use of occlusive dressings increases the percutaneous absorption of corticosteroids; their extensive use increases the possibility of systemic effects and is therefore not advisable. For patients with extensive lesions, it may be preferable to use a sequential approach, treating one portion of the body at a time. The patient should be kept under close observation if treated with large amounts of topical corticosteroid or with the occlusive technique over a prolonged period of time.

Occlusive dressings should not be applied if there is an elevation of body temperature.

The product should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation.

The risks associated with sudden discontinuation after prolonged use of corticosteroids are exacerbation or recurrence of the underlying disease, adrenocortical insufficiency or steroid withdrawal syndrome.

The risk may vary as per the potency of the steroid.

Typical signs and symptoms of topical steroid withdrawal are erythema, burning pain, desquamation of the skin, pruritus etc.

Skin

Systemic side-effects may occur with topical corticosteroid preparations, particularly when these preparations are used over large areas or for an extended period of time or with occlusive dressings. A patient who has been on prolonged therapy, especially occlusive therapy, may develop adrenal suppression due to sufficient absorption of the steroid.

If local irritation or sensitization develops, DESOXI should be discontinued, and appropriate therapy instituted.

Prolonged use of topical corticosteroid products may produce atrophy of the skin and of subcutaneous tissues, particularly on flexor surfaces and on the face. If this is noted, discontinue the use of this product.

Ophthalmic

Visual disturbance may be associated with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR).

Topical corticosteroids should be used with caution on lesions close to the eyes.

7.1 Special Populations

7.1.1 Pregnant Women

The safety of topical corticosteroid preparations during pregnancy has not been established.

7.1.2 Breast-feeding

The safety of topical corticosteroid preparations during lactation has not been established. The potential benefit should be weighed in these conditions against possible hazard to the fetus or the nursing infant. When indicated, they should not be used extensively, in large amounts or for prolonged periods of time in pregnant patients or nursing mothers.

7.1.3 Pediatrics

Desoximetasone has been shown to be safe and effective in children and is indicated in this population. However, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity.

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.

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.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

The following adverse skin reactions have been reported with the use of topical steroids and are listed in an approximately decreasing order of occurrence: itching, folliculitis, striae, hypertrichosis, change in pigmentation, secondary infection, perioral dermatitis, allergic contact dermatitis, maceration of the skin, acneiform eruptions and miliaria.

Adrenal suppression has also been reported following topical corticosteroid therapy. Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful for identifying and approximating rates of adverse drug reactions in real-world use.

8.3 Less Common Clinical Trial Adverse Reactions

Desoximetasone is well tolerated; side effects have been rare. Similar to other topical corticosteroid preparations, they may cause burning sensation, dryness, itching, erythema, change in skin pigmentation, folliculitis, pyoderma, striae, telangiectasia and skin atrophy. The following reactions are reported when corticosteroid preparations are used extensively on intertriginous areas or under occlusive dressings: maceration of the skin, secondary infection, striae, miliaria, hypertrichosis and localized skin atrophy.

8.5 Post-Market Adverse Reactions

The following local adverse reactions have been 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 frequency: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, miliaria, glucocorticosteroid insufficiency. In addition, there are reports of the development of pustular psoriasis from chronic plaque psoriasis following reduction of discontinuation of potent topical steroid products.

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.

Endocrine disorders: symptoms like erythema, burning pain, desquamation of the skin, pruritus (steroid withdrawal syndrome). Hyperglycemia has been reported as a systemic adverse effects of desoximetasone administration. Adrenal suppression has been shown to occur with prolonged use of large doses of topical corticosteroids, particularly under occlusion due to increased percutaneous absorption.

Eye disorders: blurred vision and chorioretinopathy have been reported. Posterior subcapsular cataracts have been reported following systemic use of corticosteroids.

9 DRUG INTERACTIONS

9. 4 Drug-Drug Interactions

No formal drug-drug interaction studies were conducted with desoximetasone.

Co-administered drugs that can inhibit CYP3A4 (e.g., ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

9. 5 Drug-Food Interactions

Interactions with food have not been established.

9. 6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9. 7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10. 1 Mechanism of Action

Desoximetasone is primarily effective because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions.

10. 3 Pharmacodynamics

In experimental studies in laboratory animals desoximetasone was demonstrated to have potent anti-inflammatory activity when compared with other corticosteroids following local or systemic administration.

In the “Granuloma Patch Test” (with croton oil), desoximetasone showed an activity comparable to dexamethasone and approximately ten times weaker than fluocinolone.

Following oral or subcutaneous administration to rats, desoximetasone was five times

less potent than dexamethasone in inhibiting granuloma formation (induced by subcutaneously implanted cotton pellets) and in the thymolytic assay system.

A potent anti-inflammatory activity could also be demonstrated comparatively with prednisolone and hydrocortisone following local and topical administration to rats. When administered into the pouch, desoximetasone inhibited granuloma formation twice as effectively as prednisolone and seven times as effectively as hydrocortisone, but was slightly less effective than dexamethasone. When cotton pellets were impregnated with the test drugs prior to implantation, desoximetasone was 3.5 times as potent as prednisolone and six times as potent as hydrocortisone, but four times less potent than dexamethasone.

Additional investigations confirmed the potent glucocorticoid effect following systemic administration. In adrenalectomized fasted rats, the ability of desoximetasone to induce glycogen deposition in the liver was three times less than that of dexamethasone. Following subcutaneous administration, both desoximetasone and dexamethasone showed definite diuretic, natriuretic and kaliuretic effects in rats.

Following subcutaneous injection of ^{3}H-labelled desoximetasone to rats, the blood maximum concentration was observed one hour after administration. The half-life of the tested compound was 2.3 hours. The drug was rapidly eliminated in the urine and feces, with 95% of the administered radioactivity recovered within 24 hours.

The dermal absorption of ^{3}H-labelled desoximetasone was studied in rats; blood level reached a peak at 24 hours. Urinary and fecal excretion accounted for 5-10% of the applied dose. Urinary excretion was four times greater than fecal excretion with 50% of the former as unchanged drug.

11 STORAGE, STABILITY AND DISPOSAL

Store at controlled room temperature, 15-25 °C

Keep out of sight and reach of children.

12 SPECIAL HANDLING INSTRUCTIONS

Wash your hands after applying the medications.

DESOXI when used over large areas, at high doses for prolonged period or under an airtight dressing is more likely to be absorbed into the bloodstream and cause side effects.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

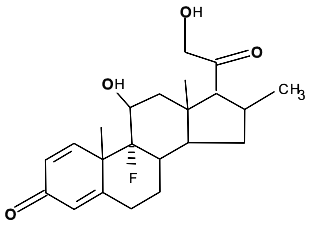
Drug Substance

Proper Name: Desoximetasone USP

Chemical Name**:** Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16-methyl-, (11ß,16α)-

Molecular Formula and Molecular Weight**:** $C_{22}H_{29}FO_4$ 376.47 g/mol

Structural Formula**:**



Desoximetasone
Compound762

Physicochemical properties:

Description: white to practically white, odorless, crystalline powder, with a melting range of 206 - 218°C. It is soluble in alcohol, acetone, chloroform and hot ethyl acetate; slightly soluble in ether and benzene and insoluble in water.

14 CLINICAL TRIALS

The clinical trial data based on which the original indication was initially authorized are not available.

14. 3 Comparative Bioavailability Studies

Desoximetasone 0.25% was shown to be superior in symptomatic improvement to standard placebo in a 2 left side/right side comparative study in patients with psoriasis (n=76), eczema (n=34) and various other steroid-responsive dermatoses (n=60).

In a number of comparative trials which reported only overall results in small groups of patients with inflammatory dermatoses, (usually psoriasis, eczema or dermatitis), desoximetasone 0.25% was usually judged to be superior to other standard steroid preparations of intermediate potency (e.g. betamethasone valerate 0.1%, triamcinolone acetonide 0.1%, fluocinolone acetonide 0.025%) and preparations of high potency (e.g. betamethasone dipropionate 0.05%, fluocinolone acetonide 0.2%, fluocinonide 0.05%) and it was often in patients with psoriasis in whom the clearest superiority of desoximetasone over the comparison drug was seen.

A one-period, randomized, vasoconstrictor, study was performed on 40 prescreened females to compare the bioavailability of DESOXI (desoximetasone) cream 0.25% manufactured by TaroPharma, A Division of Taro Pharmaceuticals Inc., with the currently marketed Topicort® (desoximetasone) cream 0.25% manufactured by Hoechst, Canada. The degree of vasoconstriction was determined both by visual assessment and with a chromameter. Statistical analyses were performed on all 40 subjects and a subset of 25 subjects who exhibited a predetermined response ratio for the visual assessment. DESOXI (desoximetasone) cream 0.25% was considered to be bioequivalent to Topicort® (desoximetasone) cream 0.25% on the basis of the statistical analysis, by Locke's method, of a subset of 25 subjects who exhibited a predetermined response ratio for the visual assessment.

Table 2 summarizes the bioequivalence comparisons for the visual data for the qualifying responders (n=25) and for all completed subjects (n=40). No statistically significant differences were detected between DESOXI (desoximetasone) cream and Topicort® (desoximetasone) cream.

Table 2: Mean Results for visual evaluation of DESOXI Cream vs Topicort® cream using ANOVA and Locke's Method for calculating confidence intervals.

		Means		Observed Difference (%)	90% Confidence Interval	
Area	**N**	**TaroPharma**	**Topicort®**		**Lower (%)**	**Upper (%)**
ANOVA	25	30.27	29.76	1.7	-8.9	12.4
ANOVA	40	30.09	30.08	0.0	-8.7	8.7
Locke's Method	25	30.05	29.53	1.8	-6.8	11.0

Statistical evaluations by ANOVA of the vasoconstriction determined with a chromameter indicated that the vasoconstriction response obtained with

DESOXI (desoximetasone) cream 0.25% was not significantly different than that obtained with Topicort® (desoximetasone) cream 0.25%.

A one-period randomized vasoconstrictor study was performed on 60 pre-screened, asymptomatic, female subjects to compare the bioavailability of DESOXI Gel 0.05% manufactured by TaroPharma, A Division of Taro Pharmaceuticals Inc., with the currently marketed Topicort® (desoximetasone) gel 0.05%, manufactured by Hoechst, Canada.

The degree of vasoconstriction was determined both by visual assessment and with a chromameter. A total of 29 of the 60 subjects for the visual results and 23 of the 60 subjects for the chromameter results who exhibited a predetermined response ratio for the assessments were included in a statistical analysis using Locke's Method for calculating confidence intervals. Results are tabulated below. Based on this analysis DESOXI (desoximetasone) gel 0.05% was considered to be bioequivalent to Topicort® (desoximetasone) gel 0.05%.

Table 3: Mean Results for visual and chromameter evaluations of DESOXI Gel vs Topicort® gel using Locke's Method for calculating confidence intervals.

TaroPharma vs Topicort	N	Means		Ratio (%)	90% Confidence Interval	
		TaroPharma	Topicort		Lower (%)	Upper (%)
Visual	29	22.70	22.42	101.2	95.0	108.2
Chromameter	23	20.99	22.82	92.0	81.7	103.8

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology

Acute Toxicity

In acute toxicity studies in mice, rats, rabbits and dogs, the oral LD_{50} (95% confidence limits) were determined as follows:

Mice: 1519 (1144-2016) mg/kg
Rats: 1469 (935-2152) mg/kg
Rabbits: 2546 (1926-3365) mg/kg

Mice and rats tolerated a single dose of 50 mg/kg of desoximetasone in various formulations when given either orally, intraperitoneally or subcutaneously.

In an acute oral toxicity study, all rats survived a dose of 36 g/kg desoximetasone gel. Toxic effects, attributed to the alcohol excipient, were decreased spontaneous activity and respiratory rate, ataxia and diminished or absent corneal, tail pinch, and righting reflexes.

Rabbits tolerated a single dose of about 5 mg/kg of desoximetasone, when topically applied to the intact skin for 24 hours. The oral LD_{50} (with 95% confidence limits) in neonatal rats were 230 (204-260) mg/kg for desoximetasone as compared to 134 (96-188) mg/kg for dexamethasone. Neonatal rats survived a single, intraperitoneal dose of 50 mg/kg of desoximetasone, whereas the same dose of dexamethasone killed 7 of 19 pups.

Subacute and Chronic Toxicity

In subacute and chronic toxicity studies the abnormal findings reflected the known systemic effects of corticosteroids.

Subcutaneous administration of desoximetasone to rats for 14 days was well tolerated at the dose of 25 mcg/kg. Doses of 100 mcg/kg inhibited the body weight gain. Rats given 400 and 1600 mcg/kg showed depression in body weight gain and decrease in weights of the thymus, adrenals and spleen.

In similar studies of 26-week duration, the effects of desoximetasone were compared to those of dexamethasone in rats and dogs. Rats given 50 mcg/kg showed a significant elevation of blood glucose. Systemic effects of corticosteroids were seen with doses of 160 mcg/kg and 500 mcg/kg of desoximetasone, the latter dose was also associated with systemic infection and death in 55% of the males and 5% of the females. Dexamethasone, at the dose of 50 mcg/kg showed similar but much less pronounced effects than desoximetasone at 500 mcg/kg. In dogs, typical and dose-related systemic corticosteroid effects were observed in animals treated with doses of 200 to 800 mcg/kg. Dexamethasone, at the dose of 200 mcg/kg, produced more frequent and more marked steroid effects than those observed with 800 mcg/kg of desoximetasone.

Dermal application of desoximetasone on intact or abraded skin was studied in rats, rabbits and dogs. Large doses of desoximetasone applied to the skin for 3 to 24 weeks produced typical local and systemic corticosteroid effects which were attributed to percutaneous absorption.

Desoximetasone failed to produce any signs of irritation when applied directly to the conjunctival sac of the rabbit eye, except for a slight lacrimation immediately following the application. When applied as an emollient cream, the preparation was very well tolerated. When 100 mg of desoximetasone gel 0.05% was instilled into one eye of six New Zealand white rabbits, the other eye serving as a control, very slight conjunctival redness was observed in one treated eye.

Carcinogenesis

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

Reproductive and Developmental Toxicology

Reproduction and teratology studies were done in mice, rats and rabbits.

Desoximetasone, given subcutaneously at the dose of 1600 mcg/kg to pregnant mice during gestational days 7-15, induced a depression of body weight gain and an expected slight increase in the incidence of cleft palate in the fetuses. By comparison, dexamethasone produced, at the lower dose of 400 mcg/kg, a higher incidence of cleft palate in the fetuses.

Desoximetasone and especially dexamethasone produced an inhibitory effect on the weight gain of adult male and female rats during the premating period. The fertility rates were not affected, however, a higher than normal number of resorptions was observed in rats given 100 mcg/kg of dexamethasone. Lower, dose-dependent birth weights of pups as compared to controls were seen in treated animals, especially in those given dexamethasone.

Administered subcutaneously to pregnant rats during gestational days 8-16, desoximetasone produced, at the doses of 400 and 100 mcg/kg, depression of body weight gain in the dams during the treatment period. A retardation of ossification of the odontoid process and an increased incidence of lumbar ribs were also noted.

Topical application of 0.25% desoximetasone ointment to the intact skin of rats during gestational days 7-16 and of rabbits during gestational days 7-19 produced typical corticosteroid effects in treated animals. The dams showed decreased weight gain, increased rate of abortion, and 'in utero' fetal death. Delivered fetuses exhibited varying degrees of growth retardation and corticosteroid induced malformations which were dose-dependent.

17 SUPPORTING PRODUCT MONOGRAPHS

1. TOPICORT (Desoximetasone Cream 0.05% w/w and 0.25% w/w, Desoximetasone Gel 0.05% w/w, Desoximetasone Ointment 0.25% w/w), submission control 260348, Product Monograph, Bausch Health, Canada Inc. (May 31, 2022).

PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDESOXI
Desoximetasone Cream USP
Desoximetasone Gel USP

Read this carefully before you start receiving **DESOXI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DESOXI**.

What is DESOXI used for?

DESOXI is used in certain skin conditions to relieve symptoms such as redness, swelling and itching.

How does DESOXI work?

The medicinal ingredient in DESOXI is desoximetasone. Desoximetasone belongs to a group of medicines called corticosteroids. Corticosteroids reduce inflammation by decreasing the body's immune response. This can relieve symptoms such as itching, redness, and swelling.

What are the ingredients in DESOXI?

Medicinal ingredient: Desoximetasone

Non-medicinal ingredients:

- **Cream 0.25% w/w:** Cetostearyl alcohol, isopropyl myristate, lanolin alcohol, mineral oil, white petrolatum and water.
- **Cream 0. 05% w/w:** Cetostearyl alcohol, isopropyl myristate, lactic acid (if necessary for pH adjustment), lanolin alcohol, mineral oil, sodium edetate, white petrolatum and water.
- **Gel 0.05% w/w:** Carbomer 940 (Carbopol® 980), disodium EDTA, docusate sodium, isopropyl myristate, SD ethanol (containing denatonium benzoate, or sucrose ocataacetate as a denaturant), trolamine and water

DESOXI comes in the following dosage forms:

- Cream 0.25% w/w.
- Cream 0.05% w/w.

- Gel 0.05% w/w.

Do not use DESOXI if:

- You are allergic or had a history of allergies to desoximetasone or any of the other ingredients in DESOXI.
- You have an untreated infection involving the skin from a bacteria, fungus such as tuberculosis or syphilis
- You have a viral disease of the skin, such as chicken pox, smallpox or herpes.

Desoxi should **not** be applied:

- to your eyes
- to large areas of the body unless advised by your healthcare professional. You may be at a higher risk of experiencing side effects if you apply DESOXI:
    - to large areas of the body
    - at high doses
    - under an airtight dressing

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive DESOXI. Talk about any health conditions or problems you may have, including if you:

- have stasis dermatitis (inflammation of the skin) and other skin diseases associated with impaired circulation
- have adrenal gland problems. DESOXI can affect how your adrenal glands work.
- have a condition for which you were previously or are currently taking other corticosteroid drugs. Use of more than one corticosteroid at the same time or close in time may increase your chance of developing adrenal gland problems.
- have eye problems, such as cataracts. Talk to your healthcare professional if you notice any change to your eyes or eyesight. Cataracts, glaucoma or central serous chorioretinopathy have been reported in patients using topical corticosteroids. Use with caution if you have lesions (broken skin) close to the eyes
- have a skin infection.
- are pregnant or trying to become pregnant.
- are breast feeding.

Other warnings you should know about:

- The use of DESOXI may cause high blood sugar.
- Covering the treated area can increase the amount of medicine absorbed through your skin. This may increase your chance of developing adrenal

gland problems. You should not cover the treated skin area with a bandage or other covering unless your healthcare professional tells you to. Using DESOXI for long time, over large areas of skin or on broken skin can also increase the amount of medicine absorbed through your skin.

- Using DESOXI for a long time may cause thinning of the skin. If you notice your skin thinning, speak to your healthcare professional.
- If you experience symptoms such as blurred vision or other visual disturbances, including decrease in visual acuity, see an ophthalmologist for evaluation of any serious eye conditions.
- You may develop contact dermatitis (allergic skin reaction) while using DESOXI. Tell your healthcare professional if your skin is not healing or worsens.
- If you need to stop taking DESOXI suddenly after prolonged use make sure you talk to your doctor before stopping the medication.
- Long term use to corticosteroids in children may interfere with their growth and development. Children may be at greater risk of experiencing side effects compared to older patients. These side effects may include:
    - adrenal gland problems (HPA axis suppression and Cushing's syndrome)
    - build-up of pressure around the brain

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DESOXI:

- It is NOT known whether DESOXI interacts with other medication.
- Some medicines may affect how DESOXI works and may make it more likely that you will have side effects:
    - ritonavir (used for HIV infection).
    - itraconazole (used for fungal infections).

How DESOXI is given:

- DESOXI is to be used only as directed by your healthcare professional. Do not use more of it, do not use it more often, or do not use it for a longer period of time than your doctor has specified.
- DESOXI is only for external use. Do not take it by mouth. Do not put this medicine on the face, underarms, or groin areas unless your doctor has instructed you to do so.
- Do not use DESOXI on or near in the eyes or eyelids. If you get DESOXI in your eye, flush it with cold water right away

- Do not wrap or bandage the treated area unless your healthcare professional has told you to do so.
- Contact your healthcare professional if your skin disease gets worse or there is no improvement in your condition within one week.

Usual dose

- Apply a small amount of DESOXI to affected areas of skin twice daily.
- Rub in gently and completely.

Overdose:

If you think you, or a person you are caring for, have used too much DESOXI, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using DESOXI?

These are not all the possible side effects you may have when taking DESOXI. If you experience any side effects not listed here, tell your healthcare professional.

- Stretch marks
- Rash around the mouth
- Redness, rash, tears or scrapes
- Application site pain or burning/stinging sensation
- Peeling and oozing of the skin
- Itching of the skin
- Irritation
- Dryness
- Inflamed hair follicles (folliculitis)
- Excessive hair growth over the body (hypertrichosis)
- Acneiform eruptions, a type of acne
- Change in skin pigmentation
- Maceration of the skin. In this condition, the skin may feel soft, wet or soggy to touch.
- Secondary infection
- Spider veins (telangiectasia)
- Heat rash (miliaria)
- Blurred vision

If you experience symptoms such as blurred vision or other visual disturbances, including decrease in visual acuity, see an ophthalmologist for evaluation of any serious eye conditions.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Dermatitis: skin rash or sores	X		
Skin atrophy: thinning of the skin		X	
Skin Irritation at the application site: red, sore or peeling skin; burning/stinging sensation; severe itching and/or dryness	X		
COMMON			
Allergic reactions: rash, hives, swelling of the skin			X
Adrenal suppression (low levels of cortisol in blood): worsening fatigue and muscle weakness, loss of appetite, weight loss, nausea, vomiting diarrhea			X
Chorioretinopathy (fluid buildup in eye): blurred vision, a dark area in your central vision, straight lines may appear bent, crooked or irregular in your affected eye, objects may appear smaller or further away than they are, when you look at a white object, it may appear to have a brownish tinge or appear duller in color			X
Cushing's syndrome (excess cortisol secretion): rounded “moon” face, weight gain, pink or purple stretch marks (striae) on the skin, fragile skin that bruises easily, slow healing of cuts, severe fatigue, muscle weakness, headache			X

Glucocorticosteroid insufficiency (low levels of plasma cortisol): Worsening fatigue and muscle weakness, loss of appetite, weight loss, nausea, vomiting, and diarrhea			X
Hyperglycemia (excess of glucose in the bloodstream): frequent urination, increased thirst, blurred vision, fatigue, headache, fruity-smelling breath, nausea and vomiting, shortness of breath, dry mouth, weakness, confusion, coma and abdominal pain			X
UNCOMMON			
Cataracts (clouding of the lens of the eye): clouded or blurred vision, double vision, difficulty in seeing during the night, sensitivity to light and glare, need for brighter than normal, light to read or see objects, seeing halo around lights, seeing objects in faded or yellow color, eye pain, headache due to changes in vision			X
Erythema (skin rash): redness of the skin or mucous membrane			X
Intracranial hypertension (increased pressure around the brain): a ringing sound heard in one or both ears, horizontal double vision, pain in the arms or legs, blurred vision (with blinds spots in the eyes), temporary visual loss, difficulty seeing to the side, light flashes, problems with balance and spatial awareness			X
Pustular psoriasis: pustules (white or yellow, pus-filled, painful bumps) that may be surrounded by inflamed or reddened/discolored skin			X
Pyoderma (bacterial skin infection): papules, large ulcers, deep ulcers, chronic wounds			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15 and 25° C.
Keep out of reach and sight of children.

If you want more information about DESOXI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website: https://www.taro.ca/, or by calling 1-800-268-1975

This leaflet was prepared by TaroPharma, A Division of Taro Pharmaceuticals Inc.

Last Revised: September 12, 2023