PRODUCT MONOGRAPH

[Pr]TARO-AMCINONIDE

(amcinonide)

Amcinonide Cream USP, 0.1% w/w
Amcinonide Ointment USP, 0.1% w/w

Topical Corticosteroid

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	All Nonmedicinal Ingredients
Topical use	Cream 0.1% w/w	benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, and sorbitol solution 70%
	Ointment 0.1% w/w	benzyl alcohol, emulsifying wax, Tenox 2 (butylated hydroxyanisole, citric acid, propyl gallate in propylene glycol), and white petrolatum.

INDICATIONS AND CLINICAL USE

TARO-AMCINONIDE (amcinonide) is a high potency topical corticosteroid indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses for a maximum duration of 5 days on the face, axillae, scrotum and scalp and a maximum of 3 weeks on the body.

Geriatrics (> 65 years of age): Safety and effectiveness of amcinonide in geriatric patients over 65 years of age have not been established (see WARNINGS AND PRECAUTIONS, Special Populations, Geriatrics (> 65 years of age)).

Pediatrics (<18 years of age): Safety and effectiveness of amcinonide in pediatric patients less than 18 years of age have not been established (see WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics (<18 years of age)).

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 DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Product Monograph.
- Patients who are hypersensitive to other corticosteroids.
- Patients with viral (e.g. herpes or varicella) lesions of the skin, bacterial or fungal skin infections, parasitic infections, skin manifestations relating to tuberculosis or

syphilis, eruptions following vaccinations, pruritus without inflammation, perioral dermatitis, rosacea, acne vulgaris, perianal and genital pruritus.

- Topical application to the eye.

WARNINGS AND PRECAUTIONS

General

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

TARO-AMCINONIDE Cream and Ointment should not be used under occlusion due to increased risk of systemic exposure and infection. When used under occlusive dressing, over extensive areas, or on the face, scalp, axillae, or scrotum, sufficient absorption may occur to result in adrenal suppression and other systemic effects (see WARNINGS AND PRECAUTIONS – Endocrine and Metabolism, Immune, and Ophthalmologic).

Cardiovascular

Suitable precautions should be taken when using topical corticosteroids in patients with stasis dermatitis and other skin diseases with impaired circulation.

Use of corticosteroids around chronic leg ulcers may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Endocrine and Metabolism

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical corticosteroids. Hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids (see ADVERSE REACTIONS).

Conditions which augment systemic absorption include the formulation and potency of the topical corticosteroid, the application of topical corticosteroids over large body surface areas, application to intertriginous areas (such as the axillae), frequency of application, prolonged use, or the use of occlusive dressings. Other risk factors for increased systemic effects include increasing hydration of the stratum corneum, use on thin skin areas (such as the face), and use on broken skin or in conditions where the skin barrier may be impaired.

If patients must be treated over large body surface areas, they should be evaluated periodically for evidence of HPA axis suppression (see WARNINGS AND PRECAUTIONS – Monitoring and Laboratory Tests). If HPA axis suppression or Cushing's syndrome is observed, an attempt should be made to withdraw the drug by reducing the frequency of application. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency (see ADVERSE REACTIONS).

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see the prescribing information for those products.

Under treatment with TARO-AMCINONIDE, systemic undesirable effects (see ADVERSE REACTIONS and OVERDOSAGE) may occur. This is dependent on the absorption of large quantities of the active ingredient through the skin. It must therefore be ensured that the specified duration of treatment (see DOSAGE AND ADMINISTRATION) is not exceeded and the size of the area treated is not more than 10-20% of the body surface area.

Pediatric patients may absorb larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface to body mass ratios as compared with adult patients (see WARNINGS AND PRECAUTIONS – Special Populations, Pediatrics).

Immune
Topical corticosteroids may increase the risk of infections including aggravation of cutaneous infection, masked infection and secondary infections. In particular, bacterial infection is encouraged by the warm, moist conditions within skin-fold areas, or caused by occlusive dressings. If concomitant skin infections develop, TARO-AMCINONIDE should be discontinued and antimicrobial therapy should be administered.

Ophthalmologic
Topical corticosteroids should be used with caution on lesions close to the eye because systemic absorption may cause increased intraocular pressure, glaucoma or cataracts.

Sensitivity
Local hypersensitivity reactions (see ADVERSE REACTIONS) may resemble symptoms of the condition under treatment. If hypersensitivity reactions occur, TARO-AMCINONIDE should be discontinued and appropriate therapy initiated.

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

Sexual Function/Reproduction
There are no data in humans to evaluate the effect of topical corticosteroids on fertility. Corticosteroids have been shown to impair fertility in animal studies.

Skin
Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis careful patient supervision is important.

If significant irritation develops, TARO-AMCINONIDE should be discontinued and appropriate therapy should be instituted.

Prolonged use of topical corticosteroid preparations may produce striae or atrophy of the skin or subcutaneous tissue. Topical corticosteroids should be used with caution on lesions of the face, groin, and axillae as these areas are more prone to atrophic changes than other areas of the body. Frequent observation is important if these areas are to be treated. If skin atrophy is observed, treatment should be discontinued.

Special Populations

Pregnant Women: Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development. The relevance of this finding to humans has not been established.

There are no adequate and well-controlled studies of amcinonide in pregnant women. Administration of amcinonide during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the fetus. The minimum quantity should be used for the minimum duration.

Due to the expected systemic re-sorption of the active ingredient, intrauterine growth disorders and atrophy of the adrenal cortex of the fetus as observed following long-term oral therapy with glucocorticoids cannot be excluded with long-term use of amcinonide and its use on large areas.

Nursing Women: The safe use of topical corticosteroids during lactation has not been established.

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human breast milk.

Because many drugs are excreted in human milk, caution should be exercised when amcinonide is administered to a nursing woman. Administration of amcinonide during lactation should only be considered if the expected benefit to the mother outweighs the risk to the infant. Nursing mothers must not apply amcinonide to the breast area in order to prevent direct contact of the nursing infant with the active ingredient.

It is not known whether amcinonide is excreted into breast milk. If its use is required on large areas during lactation, nursing mothers should cease nursing.

Pediatrics (<18 years of age): The safety of amcinonide has not been studied in pediatric patients.

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 also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment.

Adverse effects including striae have been reported with 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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Chronic corticosteroid therapy may interfere with the growth and development of children.

Geriatrics (> 65 years of age): The safety of amcinonide has not been studied in geriatric patients.

In general, topical corticosteroids should be used cautiously in elderly patients, reflecting their increased skin fragility and greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant disease or other drug therapy. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs.

There are no adequate and well-controlled studies of amcinonide in geriatric patients. For geriatric patients over 65 years of age, the minimum quantity should be used for the minimum duration (see DOSAGE AND ADMINISTRATION).

Patients with renal / hepatic impairment: The safety of amcinonide has not been studied in patients with renal or hepatic impairment.

In case of systemic absorption, metabolism and elimination may be delayed leading to increased risk of systemic toxicity.

There are no adequate and well controlled studies of amcinonide in patients with renal or hepatic impairment. For patients with renal or hepatic impairment, the minimum quantity should be used for the minimum duration (see DOSAGE AND ADMINISTRATION).

Monitoring and Laboratory Tests

The cosyntropin ($ACTH_{1-24}$) stimulation test may be helpful in evaluating patients for HPA axis suppression.

ADVERSE REACTIONS

Post-Market Adverse Drug Reactions

The following adverse reactions are reported when topical corticosteroids are used as recommended. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish causal relationship to drug exposure.

Endocrine disorders: Hypothalamic-pituitary adrenal (HPA) axis suppression, cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, hyperglycemia/glucosuria, hypertension, increased weight/obesity, decreased endogenous cortisol levels, steroid withdrawal syndrome

Eye disorders: glaucoma, cataract subcapsular

Gastrointestinal disorders: upper abdominal pain

General Disorders and Administration Site Conditions: Application site irritation/pain.

Immune system disorders: local hypersensitivity (see **Skin and subcutaneous tissue disorders**)

Infections and infestations: secondary infection

Investigations: Decreased glucose tolerance has also been reported

Skin and subcutaneous tissue disorders: skin striae, skin atrophy, telangiectasia, purpura-like bleeding, acne, dermatitis, hypertrichosis, skin depigmentation, erythema, burning sensation, pruritus, eczema, dryness, itching, local irritation, atrophy of the subcutaneous tissues, pustules, miliaria, folliculitis, pyoderma, allergic contact dermatitis, acneiform eruptions, perioral dermatitis, rash, urticaria, pustular psoriasis, skin wrinkling, alopecia, trichorrhexis, skin infection.

Vascular disorders: thrombosis

DRUG INTERACTIONS

Overview

No clinical trials were specifically designed to assess potential drug-drug, drug-food, drug-herb, or drug-laboratory interactions with amcinonide.

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.

Latex
Treatment with amcinonide in the genital or anal area with the simultaneous use of latex products (e.g. condoms, diaphragms) can result in reduction in the reliability and therefore impairment of the safety of these products due to the excipients.

Drug-Drug Interactions
Interactions with other drugs have not been established.

Drug-Food Interactions
Interactions with food have not been established.

Drug-Herb Interactions
Interactions with herbal products have not been established.

Drug-Laboratory Interactions
Interactions with laboratory tests have not been established.

DOSAGE AND ADMINISTRATION

Dosing Considerations

- Patients/caregivers should be instructed to use the minimum quantity of TARO-AMCINONIDE for the shortest duration of time necessary to achieve the desired therapeutic benefit because of the potential for corticosteroids to suppress the hypothalamic-pituitary-adrenal (HPA) axis and cause skin atrophy (See WARNINGS AND PRECAUTIONS).

- If the condition worsens or does not improve within 2 weeks, treatment and diagnosis should be re-evaluated.

- Use in pediatric patients is not recommended. Pediatric patients are more likely to develop local and systemic toxicity from equivalent doses of topical corticosteroids because of their larger skin surface to body weight ratios.

- Geriatric patients may be more susceptible to percutaneous absorption and the potential effects of systemic absorption. The greater frequency of decreased hepatic or renal function in the elderly may delay elimination if systemic absorption occurs.

Recommended Dose and Dosage Adjustment

Apply a thin layer to affected area once or twice daily and gently rub in. Allow adequate time for absorption after each application before applying an emollient.

TARO-AMCINONIDE should not be used for longer than **5 days on the face, axillae, scrotum and scalp** (see WARNINGS AND PRECAUTIONS).

TARO-AMCINONIDE should not be used for longer than **2 to 3 weeks on the body** (see WARNINGS AND PRECAUTIONS). If the condition worsens or does not improve within 2 weeks, treatment and diagnosis should be re-evaluated.

Avoid abrupt discontinuation of TARO-AMCINONIDE therapy once control is achieved as rebound of pre-existing dermatoses can occur. Continue an emollient as maintenance therapy.

Pediatrics (< 18 years of age): The safety and effectiveness of amcinonide in pediatric patients less than 18 years of age have not been established (see WARNINGS AND PRECAUTIONS - Special Populations, Pediatrics (< 18 years of age)).

Geriatrics (> 65 years of age): Amcinonide should be used with caution in geriatric patients due to increased risk of renal or hepatic impairment in this population. The minimum quantity should be used for the shortest duration to achieve the desired therapeutic benefit (see WARNINGS AND PRECAUTIONS - Special Populations, Geriatrics (> 65 years of age)).

Renal/Hepatic Impairment: In patients with renal or hepatic impairment, the minimum quantity should be used for the shortest duration to achieve the desired therapeutic benefit (see WARNINGS AND PRECAUTIONS - Special Populations, Patients with renal / hepatic impairment).

Missed Dose

In the event of a missed dose, TARO-AMCINONIDE should be applied as soon as possible after the missed dose is remembered. If this is close to the scheduled application time or the next dose, the patient should wait and apply the next scheduled dose. The usual schedule should be resumed thereafter.

Administration

- TARO-AMCINONIDE is for topical use only.
- Use with occlusive dressings is not recommended (see WARNINGS AND PRECAUTIONS).
- TARO-AMCINONIDE is not for use in or near the eye or on other mucous membranes.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see WARNINGS AND PRECAUTIONS). In the event of overdose or misuse, the features of hypercortisolism may occur (see ADVERSE REACTIONS).

Excessive prolonged use or misuse may suppress hypothalamic-pituitary-adrenal (HPA) axis function, resulting in secondary adrenal insufficiency. If symptoms of HPA axis suppression occur, amcinonide should be withdrawn gradually by reducing the frequency of application, or by substituting a less potent corticosteroid because of the risk of glucocorticosteroid insufficiency. Further management should be as clinically indicated. If toxic effects occur, TARO-AMCINONIDE should be discontinued and symptomatic therapy should be administered.

STORAGE AND STABILITY

TARO-AMCINONIDE cream and ointment should be stored at controlled room temperature 15°-30°C. Keep the container tightly closed. Avoid freezing. Keep out of the sight and reach of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

TARO-AMCINONIDE cream is a white cream. TARO-AMCINONIDE ointment is a white to yellowish smooth ointment.

TARO-AMCINONIDE cream 0.1% contains 1 mg/g amcinonide in a base of benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, and sorbitol solution 70%.

TARO-AMCINONIDE ointment 0.1% contains 1 mg/g amcinonide in an ointment base of benzyl alcohol, emulsifying wax, Tenox 2 (butylated hydroxyanisole, citric acid, propyl gallate in propylene glycol), and white petrolatum.

TARO-AMCINONIDE ointment is recommended for topical use and available in 15, 30, and 60 grams laminate tubes. TARO-AMCINONIDE cream is recommended for topical use and available in 15, 30, and 60 grams laminate tubes, and in 100 grams polypropylene jars.

PART II: SCIENTIFIC INFORMATION

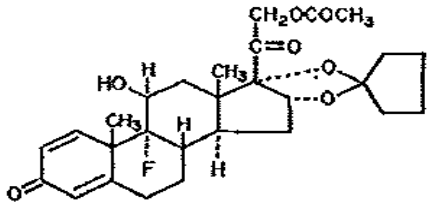
PHARMACEUTICAL INFORMATION

DRUG SUBSTANCE

Proper name: Amcinonide USP

Chemical name: 9-Fluoro-llß, 16α, 17, 21-tetrahydroxypregna-l, 4-diene-3, 20-dionecyclic 16, 17-acetal with cyclopentanone, 21-acetate

Structure:



Molecular Formula: $C_{28}H_{35}FO_7$
Molecular Weight: 502.59
Description: Amcinonide occurs as a white to cream coloured crystalline powder, having not more than a slight odour.
Melting Point: 248 ° - 252 °C
Solubility: Amcinonide is soluble in alcohol, methanol; sparingly soluble in acetone and chloroform; slightly soluble in ether and insoluble in water.

COMPOSITION OF DOSAGE FORM
TARO-AMCINONIDE cream 0.1 % contains 1 mg/g amcinonide in a base of benzyl alcohol (as preservative), emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, and sorbitol solution 70%.

TARO-AMCINONIDE ointment 0.1% contains 1 mg/g amcinonide in an ointment base of benzyl alcohol, emulsifying wax, Tenox 2 (butylated hydroxyanisole, citric acid, propyl gallate in propylene glycol), and white petrolatum.

STABILITY AND STORAGE RECOMMENDATIONS
TARO-AMCINONIDE cream and ointment should be stored at controlled room temperature 15°-30°C. Keep the container tightly closed. Avoid freezing.

AVAILABILITY OF DOSAGE FORM
TARO-AMCINONIDE ointment is recommended for topical use and available in 15, 30 and 60 gram laminate tubes. TARO-AMCINONIDE cream is recommended for topical use and available in 15, 30, and 60 grams laminate tubes, and in 100 grams polypropylene jars.

CLINICAL TRIALS

A one-period, randomized, vasoconstrictor study was performed with 35 prescreened, qualifying subjects to compare TARO-AMCINONIDE cream 0.1 %, manufactured by Taro Pharmaceuticals Inc. with the Canadian marketed product, Cyclocort® Cream 0.1 %, manufactured by Stiefel Canada Inc.

A 10µl amount of cream was applied to the subject's forearm and left in place for seven minutes. The degree of vasoconstriction was determined with a Chroma Meter at predose, 0, 2, 4, 6, 8, 10, 12, 20 and 24 hours after removal.

The area under the response curve from 0-24 hours was determined using the Chroma Meter data and results are tabulated below:

Summary of Bioequivalence Evaluation

Number of Subjects	Mean Area Under the Response Curve		Test to Reference Ratio %	90% Confidence Interval	
	TARO AMCINONIDE Cream 0.1% (Taro Pharmaceutical Inc.)	Cyclocrt® Cream 0.1% (Stiefel Canada Inc.)		Low	High
35	-11.81	-11.84	99.8	83.6	118.9

Statistical evaluation of the vasoconstrictor activity determined by the Chroma Meter indicated that the vasoconstrictor response from Taro Pharmaceutical Inc.'s Amcinonide Cream 0.1 % was not statistically different from that obtained from Cyclocort® Cream 0.1%.

A one-period, randomized, vasoconstricotr study was performed with 46 prescreened, qualifying subjects to compare TARO-AMCINONIDE ointment 0.1 %, manufactured by Taro Pharmaceuticals Inc. with the Canadian marketed product Cyclocort® Ointment 0.1%, manufactured by Stiefel Canada Inc.

A 10 µl amount of ointment was applied to the subject's forearm and left in place for 35 minutes. The degree of vasoconstriction was determined with a Chroma Meter at predose, 0, 2, 4, 6, 8, 10, 12, 20 and 24 hours after removal.

The area under the response curve from 0-24 hours was determined using the Chroma Meter data and results are tabulated below:

Summary of Bioequivalence Evaluation

Number of Subjects	Mean Area Under the Response Curve		Test to Reference Ratio %	90% Confidence Interval	
	TARO AMCINONIDE Ointment 0.1% (Taro Pharmaceutical Inc.)	Cyclocrt® Ointment 0.1% (Stiefel Canada Inc.)		Low	High
46	-9.08	-9.4	99.6	80.9	115.7

Statistical evaluation ofthe vasoconstrictor activity determined by the Chroma Meter indicated that the vasoconstrictor response from Taro Pharmaceutical Inc.'s Amcinonide Ointment 0.1 % was not statistically different from that obtained from Cyc1ocort® Ointment 0.1 %.

REFERENCE

1. Product Monograph for Cyclocort® Amcinonide Cream 0.1% USP, Ointment 0.1% USP, and Lotion 0.1% USP, Date of Preparation: November 4, 2014, GlaxoSmithKline Inc. Submission Control No. 175944.

PART III: CONSUMER INFORMATION

PrTARO-AMCINONIDE

(amcinonide)

Amcinonide Cream USP, 0.1% w/w
Amcinonide Ointment USP, 0.1% w/w

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TARO-AMCINONIDE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
TARO-AMCINONIDE is used to help relieve the redness and itchiness of certain skin problems.

What it does:
TARO-AMCINONIDE contains amcinonide which belongs to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin.

When it should not be used:
Do not use TARO-AMCINONIDE if you are allergic to amcinonide, other corticosteroids, or to any other ingredients in TARO-AMCINONIDE (see **What the nonmedicinal ingredients are**).

Do not apply TARO-AMCINONIDE on the areas of the skin that have:

- bacterial, fungal, parasitic, viral skin infections (e.g. herpes simplex, chicken pox), tuberculosis or syphilis skin lesions, or a skin reaction following a recent vaccination.

- acne, rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules)), rashes around the mouth, itchy skin which is not inflamed, itchy skin around the anus or genitals.

Do not apply in or near the eye.

If you think any of these apply to you, don't use TARO-AMCINONIDE until you have checked with your doctor or pharmacist.

What the medicinal ingredient is:
Amcinonide

What the nonmedicinal ingredients are:
The nonmedicinal ingredients of TARO-AMCINONIDE Cream are benzyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, and sorbitol solution.

The nonmedicinal ingredients of TARO-AMCINONIDE Ointment are benzyl alcohol, emulsifying wax, Tenox 2 (butylated hydroxyanisole, citric acid, propyl gallate in propylene glycol), and white petrolatum.

What dosage forms it comes in:
TARO-AMCINONIDE ointment is available in 15, 30, and 60 grams laminate tubes. TARO-AMCINONIDE cream is available in 15, 30, and 60 grams laminate tubes, and in 100 grams polypropylene jars.

WARNINGS AND PRECAUTIONS

Apply just enough TARO-AMCINONIDE to cover the affected areas. TARO-AMCINONIDE can get into the blood and cause side effects.

Always follow your doctor's instructions.

Do **NOT** use TARO-AMCINONIDE with occlusive dressings such as a bandage, or cover the treated areas tightly.

TARO-AMCINONIDE is more likely to cause side effects when used:

- over large areas
- on sensitive areas such as the face, scalp, skin fold areas like the armpit and groin
- on broken skin for a long time

Inform any doctor you consult that you are using or you have previously used corticosteroids.

Before using TARO-AMCINONIDE, talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant.
- you are breastfeeding. It is not known if TARO-AMCINONIDE will appear in breast milk. You should only use TARO-AMCINONIDE while breastfeeding if you and your doctor decide that the benefits to the mother outweigh the risks to the baby. If you do use TARO-AMCINONIDE when breastfeeding, do not use on your breast area to ensure that the baby does not accidentally get it in their mouth. If TARO-AMCINONIDE is used on large areas of body, you should stop

breastfeeding.
- you have inflammatory skin diseases in the leg as a result of impaired circulation (such as stasis dermatitis).
- you have problems with your kidney or liver. You may need to use a smaller amount of TARO-AMCINONIDE or use it less often.
- you have any skin disease around a leg ulcer; use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.

While using TARO-AMCINONIDE, talk to your doctor or pharmacist if:
- you develop any skin infection
- you have an allergic reaction
- you develop significant skin irritation
- you experience skin thinning or softening
- your condition worsens or does not improve
- you develop raised bumps with pus under the skin

TARO-AMCINONIDE should be used with caution on the scalp, face or in skin fold areas, such as the groin or the armpit since these areas are more prone to skin thinning.

Avoid applying TARO-AMCINONIDE in or near the eye, or other mucous membranes. In case of contact, wash with water. Absorption in the body may cause increased pressure in the eye (glaucoma), or a cloudy lens in the eye (cataracts).

Children absorb larger amounts of topical corticosteroids and therefore, may be more likely to develop side effects. **TARO-AMCINONIDE is not recommended for use in children under 18 years of age.**

INTERACTIONS WITH THIS MEDICATION

It is **NOT** known whether TARO-AMCINONIDE interacts with other medication. Some medicines may affect how TARO-AMCINONIDE works, or make it more likely that you'll have side effects. Examples of these medicines include:

- Ritonavir (for HIV)
- Itraconazole (for fungal infections)

Tell your doctor or pharmacist about all your other medications, including medicines that you bought without prescription and natural health products.

Treatment with TARO-AMCINONIDE in the genital or anal area with the simultaneous use of latex products (e.g. condoms, diaphragms) can result in reduction in the reliability and therefore impairment of the safety of these products.

PROPER USE OF THIS MEDICATION

Use the minimum quantity of TARO-AMCINONIDE for the shortest amount of time necessary to achieve the desired results. This is especially important if you are 65 years or older or have liver or kidney disease.

Check with your doctor or pharmacist if you are not sure.

TARO-AMCINONIDE is for use on the skin only. It is **NOT** for use in the eyes or on other mucous membranes.

Usual dose:
Apply a thin film to the affected areas once or twice a day. The number of times you use your medicine may be reduced as your skin gets better or your doctor may prescribe a weaker steroid for you to use instead.

Use for a maximum of:
- 5 days on the face, scalp, skin-fold areas like the armpit and groin.
- 2-3 weeks on the body. If your condition worsens or no improvement is seen within 2 weeks, contact your doctor.

It is important to not stop using TARO-AMCINONIDE suddenly or your skin condition could flare up again.

Use TARO-AMCINONIDE only as directed by your health care provider. **Do NOT use more of it, do NOT use it more often and do NOT use it for a longer period of time than your health care provider recommended.** Using too much TARO-AMCINONIDE may increase your chances of unwanted and sometimes dangerous side effects.

This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

How to Apply TARO-AMCINONIDE:

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- Excess product should not be returned to the container, since it may cause contamination.
- If you are also using an emollient (moisturising) preparation allow time for TARO-AMCINONIDE to be absorbed after each application before applying the emollient.
- Your doctor may recommend using a moisturizer as maintenance therapy.
- Do not use occlusive dressings such as a bandage, or cover the treated areas tightly.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you forget to use TARO-AMCINONIDE, apply it as soon as you remember. If it is close to the time scheduled to apply your next dose, wait and apply your next scheduled dose and then continue as before. Do not apply extra TARO-AMCINONIDE to make up for missed doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines TARO-AMCINONIDE can have side effects although not everybody gets them. Side effects will affect your skin and may have an effect on other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

If your skin condition gets worse or your skin becomes swollen during treatment. You may be allergic to the medicine or need other treatment. Stop using TARO-AMCINONIDE and tell your doctor as soon as possible.

The following side effects have been reported in patients using topical corticosteroids:

Common side effects
- itchy skin
- local skin burning or pain

Very rare side effects
Use of TARO-AMCINONIDE for a long period of time, over a large body surface, or use under an airtight dressing, may cause the following symptoms:
- increased weight
- moon face/rounding of the face, obesity
- skin thinning (this may cause stretch marks), skin wrinkling, skin dryness, the appearance of blood vessels under the surface of your skin (telangiectasia), changes to the colour of your skin, skin infection
- increased body hair, hair loss/lack of hair growth/damaged looking hair
- allergic reaction, irritation, itching or pain at the site of application
- inflammation of hair follicles
- worsening of condition
- redness, rash or hives
- secondary infection
- allergic contact dermatitis/dermatitis (a type of eczema)
- upper abdominal pain
- prickly heat rash
- steroid withdrawal syndrome (symptoms may include weight loss, fatigue, nausea, diarrhea and abdominal pain)
- acne

If you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Other symptoms that may only show in blood tests or when your doctor gives you a medical examination are: decreased hormone cortisol levels in your blood, increased sugar levels in your blood or urine, high blood pressure, cloudy lens in the eye (cataract), increased pressure in the eye (glaucoma), as well as weakening of the bones through gradual mineral loss (osteoporosis) and additional tests may be needed after your medical examination to confirm whether you have osteoporosis.

If any of the side effects listed becomes severe or troublesome, tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Allergic reactions: rash, hives, swelling of the skin, chills, fever, muscle aches or pains or flu-like symptoms occurring with or before a skin rash.			✓
Cushing's syndrome: weight gain, moon face / rounding of the face and obesity.			✓
Hyperglycemia (increased blood sugar): frequent urination, thirst and hunger.		✓	
Glucosuria (sugar in urine): excessive or sweet smelling urine.		✓	
Hypertension (high blood pressure): headaches, vision disorders, nausea and vomiting.		✓	
Osteoporosis: weakening of the bones potentially leading to an increased risk of bone fracture.		✓	
Glaucoma or cataracts: blurred vision, increased pressure in your eyes, eye pain.			✓

This is not a complete list of side effects. For any unexpected effects while taking TARO-AMCINONIDE, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15° - 30°C). Keep the container tightly closed. Avoid freezing.

Keep out of the sight and reach of children.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect; (http://hc-sc.gc.ca/dph-mps/medeff/index-eng.php)
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9
    Postage paid labels and the Consumer Side Effect Form are available at MedEffect (http://hc-sc.gc.ca/dph-mps/medeff/index-eng.php)

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
http://www.taro.ca

or by contacting the sponsor, Taro Pharmaceuticals Inc., at:
1-800-268-1975

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