

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VERDESO Foam safely and effectively. See full prescribing information for VERDESO Foam.

Verdeso® (desonide) Foam, 0.05%
For topical use only

Initial U.S. Approval: 1972

-----INDICATIONS AND USAGE-----

- Verdeso Foam is a corticosteroid indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older. (1)

-----DOSAGE AND ADMINISTRATION-----

- Verdeso Foam should be applied to the affected area(s) twice daily. (2)
- Discontinue therapy when control has been achieved. (2)
- If no improvement is seen within 4 weeks, reassess diagnosis. (2)
- Unless directed by a physician, do not use with occlusive dressings. (2)
- Verdeso Foam is not for oral, ophthalmic, or intravaginal use. (2)
- The safety and efficacy of Verdeso Foam has not been established beyond 4 weeks of use. (2)

-----DOSAGE FORMS AND STRENGTHS-----

- White to off-white petroleum-based emulsion aerosol foam containing 0.05% desonide. (3)

-----CONTRAINDICATIONS-----

- None.

-----WARNINGS AND PRECAUTIONS-----

- Verdeso Foam has been shown to produce reversible HPA axis suppression. (5.1, 8.4, 14)

- Systemic effects of topical corticosteroids may also include manifestations of Cushing's syndrome, hyperglycemia, facial swelling, glycosuria, withdrawal syndrome, and growth retardation in children. (5.1)
- Systemic absorption may require evaluation for HPA axis suppression. (5.1, 5.5)
- Modify use should HPA axis suppression develop. (5.1)
- Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption. (5.1)
- Pediatric patients may be more susceptible to systemic toxicity. (5.1, 8.4, 12.2)
- Concomitant therapy with topical corticosteroids should be used with caution because a cumulative effect may occur. (5.1)
- Discontinue use if irritation develops. (5.2)
- Initiate appropriate therapy if concomitant skin infections develop. (5.3)
- The propellant in Verdeso Foam is flammable. Avoid fire, flame, or smoking during and immediately following application. (5.4)

-----ADVERSE REACTIONS-----

- The most common adverse reactions (>1%) are upper respiratory tract infection, cough, application site burning, headache, viral infection, and increased blood pressure. (6.1)
- In post-marketing reports, the most common adverse reactions were application site irritation followed by application site erythema. (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Stiefel Laboratories, Inc. at 1-888-784-3335 (STIEFEL) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

-----USE IN SPECIFIC POPULATIONS-----

- Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen since these patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved patient labeling.

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

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Verdeso[®] (desonide) Foam, 0.05% is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Verdeso Foam for the minimum amount of time necessary to achieve the desired results because of the potential for Verdeso Foam to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Treatment should not exceed 4 consecutive weeks.

2 DOSAGE AND ADMINISTRATION

Verdeso Foam is not for oral, ophthalmic, or intravaginal use.

A thin layer of Verdeso Foam should be applied to the affected area(s) twice daily. Shake the can before use. Verdeso Foam should be dispensed by inverting the can (upright actuation will cause loss of the propellant which may affect product delivery). Dispense the smallest amount of foam necessary to adequately cover the affected area(s) with a thin layer.

The medication should not be dispensed directly on the face. Dispense in hands and gently massage into affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly onto the affected area. Take care to avoid contact with the eyes or other mucous membranes.

Patients should dispense the smallest amount of foam as necessary to adequately cover the affected area with a thin layer. Therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, reassessment of diagnosis may be necessary. The safety and efficacy of Verdeso Foam has not been established beyond 4 weeks of use. Treatment should not exceed 4 consecutive weeks.

Unless directed by a physician, Verdeso Foam should not be used with occlusive dressings.

3 DOSAGE FORMS AND STRENGTHS

White to off-white petrolatum-based emulsion aerosol foam containing 0.05% desonide.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hypothalamic-pituitary-adrenal Axis Suppression

Verdeso Foam has been shown to reversibly suppress the HPA axis.

Topical application of Verdeso Foam may result in systemic absorption and effects including HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, facial swelling, glycosuria, withdrawal, and growth retardation in children. Use of Verdeso Foam for longer than four weeks may suppress the immune system [see *Nonclinical Toxicology (13.1)*].

Conditions that augment systemic absorption include the application of topical corticosteroids over large body surface areas, prolonged use, or the addition of occlusive dressings. Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression.

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.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the cosyntropin stimulation test. The laboratory suppression was transient; all subjects had returned to normal when tested 4 weeks post treatment.

Pediatric patients may be more susceptible than adults to systemic toxicity from equivalent doses of Verdeso Foam due to their larger skin surface to body mass ratios. [see *Use in Specific Populations (8.4)*].

Concomitant therapy with topical corticosteroids should be used with caution because a cumulative effect may occur.

5.2 Skin Irritation

Verdeso Foam may cause local skin adverse reactions [see *Adverse Reactions (6)*]. If irritation develops, Verdeso Foam should be discontinued and appropriate therapy instituted. 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.

5.3 Concomitant Skin Infections

If concomitant skin infections are present or develop, the use of an appropriate antifungal, antibacterial or antiviral agent should be instituted. If a favorable response does not occur promptly, use of Verdeso Foam should be discontinued until the infection has been adequately controlled.

5.4 Flammable Contents

The contents of Verdeso Foam include alcohol and propane/butane, which are flammable. Avoid fire, flame and/or smoking during and immediately following application. Do not puncture and/or incinerate the containers. Do not expose containers to heat and/or store at temperatures above 120°F (49°C).

5.5 Laboratory Tests

The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

6 ADVERSE REACTIONS**6.1 Clinical Trial Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rate 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 clinical practice.

In a controlled clinical study of 581 patients 3 months to 17 years of age, adverse reactions occurred at the application site in 6% of subjects treated with Verdeso Foam and 14% of subjects treated with Vehicle Foam. Other commonly reported adverse reactions for Verdeso Foam and Vehicle Foam are noted in Table 1.

Table 1—Adverse Reactions in the Clinical Trial

<i>Adverse Reaction</i>	<i>Verdeso Foam (N=387)</i>	<i>Vehicle Foam (N=194)</i>
Upper respiratory tract infection	37 (10%)	12 (6%)
Cough	14 (4%)	3 (2%)
Application site burning	11 (3%)	15 (8%)
Viral infection	6 (2%)	0 (0%)
Elevated blood pressure	6 (2%)	1 (1%)
Headache	7 (2%)	1 (1%)
Asthma	3 (1%)	0 (0%)
Irritability	2 (1%)	0 (0%)
Pharyngitis	2 (1%)	0 (0%)
Application site atrophy	5 (1%)	0 (0%)
Application site reactions (including atrophy, striae, telangiectasia and pigmentation changes)	3 (1%)	6 (3%)

Other local adverse events occurred at rates less than 1.0%. The majority of adverse reactions were transient and mild to moderate in severity, and they were not affected by age, race, or gender.

The following additional local adverse reactions have been reported with topical corticosteroids. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, and miliaria.

6.2 Post-marketing Experience

The following adverse reactions have been identified during post approval use of Verdeso Foam: application site irritation, application site erythema, application site reactions, skin reactions, and swelling face. Because these 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.

8 USE IN SPECIFIC POPULATIONS**8.1 Pregnancy**

Teratogenic Effects: Pregnancy Category C:

There are no adequate and well-controlled studies of Verdeso Foam in pregnant women. Therefore, Verdeso Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

No long-term reproductive studies in animals have been performed with Verdeso Foam. Dermal embryofetal development studies were conducted in rats and rabbits with a desonide cream, 0.05% formulation. Topical doses of 0.2, 0.6, and 2.0 g cream/kg/day of a desonide cream, 0.05% formulation or 2.0 g/kg of the cream base were administered topically to pregnant rats (gestational days 6–15) and pregnant rabbits (gestational days 6–18). Maternal body weight loss was noted at all dose levels of the desonide cream, 0.05% formulation in rats and rabbits. Teratogenic effects characteristic of corticosteroids were noted in both species. The desonide cream, 0.05% formulation was teratogenic in rats at topical doses of 0.6 and 2.0 g cream/kg/day and in rabbits at a topical dose of 2.0 g cream/kg/day. No teratogenic effects were noted for the desonide cream, 0.05% formulation at a topical dose of 0.2 g cream/kg/day in rats and at a topical dose of 0.6 g cream/kg/day in rabbits. These doses (0.2 g cream/kg/day in rats and 0.6 g cream/kg/day in rabbits) are similar to the maximum recommended human dose based on body surface area comparisons.

8.3 Nursing Mothers

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 milk. Because many drugs are excreted in human milk, caution should be exercised when Verdeso Foam is administered to a nursing woman.

If used during lactation, Verdeso Foam should not be applied on the chest to avoid accidental ingestion by the infant.

8.4 Pediatric Use

Safety and efficacy in pediatric patients below 3 months of age have not been established and therefore the use of Verdeso Foam is not recommended.

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 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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients, ages 6 months to 17 years, in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the ACTH stimulation test. The suppression was transient; all subjects' cortisol levels had returned to normal when tested 4 weeks post treatment.

8.5 Geriatric Use

Clinical studies of Verdeso Foam did not include any subjects aged 65 or over to determine whether they respond differently from younger subjects. 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

Topically applied Verdeso Foam can be absorbed in sufficient amounts to produce systemic effects.

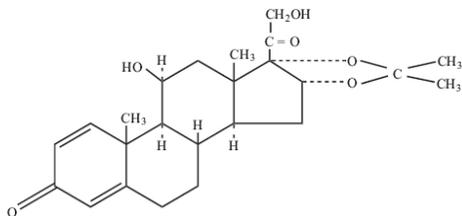
Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids.

11 DESCRIPTION

Verdeso Foam is a petrolatum-based emulsion aerosol foam containing the active ingredient desonide, a low-potency topical corticosteroid.

Chemically, desonide is (11 β ,16 α)-11,21-dihydroxy-16,17-[(1-methylethylidene)-bis(oxy)]-pregna-1,4-diene-3,20-dione.

The structural formula of desonide is represented below:



Desonide has a molecular formula of C₂₄H₃₂O₆ and a molecular weight of 416.51. Desonide is a white powder or crystal that is practically insoluble in water, sparingly soluble in ethanol and in acetone, and soluble in chloroform. Each gram of Verdeso Foam contains 0.5 mg desonide. The foam also contains anhydrous citric acid, cetyl alcohol, cyclomethicone, isopropyl myristate, light mineral oil, white petrolatum, polyoxyl 20 cetostearyl ether, potassium citrate (monohydrate), propylene glycol, purified water, sorbitan monolaurate, and phenoxyethanol as a preservative.

Verdeso Foam is dispensed from an aluminum can pressurized with a hydrocarbon (propane/butane) propellant.

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 the treatment of atopic dermatitis is unknown.

The contribution to efficacy by individual components of the vehicle has not been established.

12.2 Pharmacodynamics

In an HPA axis suppression study, 3 of 75 (4%) pediatric patients with mild to moderate atopic dermatitis covering at least 25% body surface area, who applied Verdeso Foam twice daily, experienced reversible suppression of the adrenal glands (as indicated by a 30-minute post-stimulation cortisol level \leq 18 mcg/dL) following 4 weeks of therapy. [See also *Warnings and Precautions (5.1)*, *Pediatric Use (8.4)* and *Clinical Studies (14)*].

12.3 Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the product formulation, the integrity of the epidermal barrier, and age. Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolized, primarily in the liver, and are then excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic or photo co-carcinogenic potential of Verdeso Foam or desonide. The effects of desonide on fertility have not been evaluated. In a 90-day repeat-dose toxicity study in rats, topical administration of Verdeso Foam at dose concentrations from 0.025 – 0.125% or from 0.075 to 0.375 mg/kg/day of desonide resulted in a toxicity profile consistent with long term exposure to corticosteroids including adrenal atrophy, histopathological changes in several organs systems indicative of severe immune suppression and opportunistic fungal and bacterial infections. A NOAEL could not be determined in this study. Although the clinical

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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.

Desonide revealed no evidence of mutagenic potential based on the results of two in vitro genotoxicity tests (Ames assay, mouse lymphoma cell assay) and an in vivo genotoxicity test (mouse micronucleus assay).

14 CLINICAL STUDIES

In a double-blind, randomized study of 581 patients ages 3 months to 17 years old, with mild to moderate atopic dermatitis, Verdeso Foam was applied twice daily for 4 weeks. Success was defined as the proportion of patients who had all of the following: an Investigator's Static Global Assessment (ISGA) score of clear or almost clear, a minimum improvement in the 5 point ISGA score of 2 grades from Baseline to Week 4, and a score of absent or minimal for both erythema and induration/papulation at Week 4. The results of this study are presented in the following table.

	Verdeso Foam	Vehicle Foam
Number of Patients	387	194
Patients Achieving Success	152 (39%)	18 (9%)

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Verdeso Foam is supplied in 100 g (NDC 63032-111-00) and 50 g (NDC 63032-111-50) aluminum cans.

16.2 Storage and Handling

Store at controlled room temperature 68°F to 77°F (20°C to 25°C).

WARNING

FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

Contents under pressure. Do not puncture or incinerate. Do not expose containers to heat, and/or store at temperatures above 120°F (49°C).

Avoid contact with eyes or other mucous membranes.

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (Patient Information)

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes or other mucous membranes. The medication should not be dispensed directly onto the face. Dispense in hands and gently massage into affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly on the affected area. Wash hands after use.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to the physician.
5. Patients should inform their physicians that they are using Verdeso Foam if surgery is contemplated.
6. Therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
7. Do not use other corticosteroid-containing products while using Verdeso Foam without first consulting your physician.
8. The propellant in Verdeso Foam is flammable. Avoid fire, flame or smoking during and immediately following application.

VDS:3PI

FDA-Approved Patient Labeling

PATIENT INFORMATION

Verdeso (ver-DES-o) (desonide) Foam 0.05%

Read the Patient Information that comes with Verdeso Foam before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or treatment.

What is Verdeso Foam?

Verdeso Foam is a prescription medicine used on the skin (topical) to treat mild or moderate atopic dermatitis in people 3 months of age and older.

It is not known if Verdeso Foam is safe and effective when used for longer than 4 weeks in a row. You should not use Verdeso Foam for more than 4 weeks in a row without talking with your doctor.

It is not known if Verdeso Foam is safe and effective in children younger than 3 months of age.

What should I tell my doctor before using Verdeso Foam?

Before using Verdeso Foam, tell your doctor if you:

- have a skin infection that is not healing
- have had irritation or other skin reaction to a steroid medicine in the past
- plan to have surgery
- are pregnant or plan to become pregnant. It is not known if Verdeso Foam will harm your unborn baby.
- are breastfeeding or plan to breast feed. It is not known if Verdeso Foam passes into your breast milk. If you use Verdeso Foam while breast-feeding, do not apply it to your chest area. This will help prevent your baby from swallowing Verdeso Foam.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you use another medicine on your skin for your atopic dermatitis. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I use Verdeso Foam?

- Use Verdeso Foam exactly as prescribed. Do not use more Verdeso Foam than is needed to cover the affected areas.
- Do not get Verdeso Foam in your eyes, mouth, or vagina.
- Verdeso Foam is usually applied to the affected skin areas 2 times each day.
- Talk to your doctor if your skin does not improve after using Verdeso Foam for 4 weeks.
- You should not use Verdeso Foam for more than 4 weeks in a row without talking with your doctor.
- Verdeso Foam contains alcohol. Alcohol based products are flammable. Avoid fire, flames or smoking while applying Verdeso Foam to your skin and right after you apply it.

Applying Verdeso Foam.

1. Before applying Verdeso Foam for the first time, break the tiny plastic seal at the base of the nozzle by gently pushing it back away from the seal. Shake the can before use. Remove the cap.
2. Turn the can upside down. Depress the button to dispense a small amount of Verdeso Foam into the palm of your hand or directly onto the affected skin area. Do not apply Verdeso Foam directly to your face. Use the smallest amount of Verdeso Foam needed to cover the affected areas with a thin layer.
3. Gently massage the Verdeso Foam into the affected areas until it disappears. Avoid getting the medicine in your eyes.
- 4. Do not apply directly on the face. Place in hands and gently massage affected areas of face. Take care to avoid eyes and lips. Remember to wash hands after use.**
5. Do not apply a bandage over Verdeso Foam unless your doctor tells you to.

What are the possible side effects of Verdeso Foam?

Common side effects of Verdeso Foam include:

- upper respiratory tract infection
- burning where you apply Verdeso Foam
- cough
- headache
- increased blood pressure

Tell your doctor if you have any side effects that bother you or that do not go away.

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These are not all the possible side effects of Verdeso Foam. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to Stiefel at 1-888-784-3335 (STIEFEL).

How should I store Verdeso Foam?

- Store the can of Verdeso Foam at room temperature, 68° to 77°F (20°C to 25°C). Do not place the Verdeso Foam can in the refrigerator or freezer.
- Do not break through (puncture) the Verdeso Foam can.
- Do not throw the can into fire. Verdeso Foam is flammable.
- Keep Verdeso Foam and all medicines out of the reach of children.

General information about Verdeso Foam

Do not use Verdeso Foam for a condition for which it was not prescribed. Do not give Verdeso Foam to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about Verdeso Foam. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Verdeso Foam that is written for health professionals.

What are the ingredients in Verdeso Foam?

Active ingredient: desonide

Inactive Ingredients: anhydrous citric acid, cetyl alcohol, cyclomethicone, isopropyl myristate, light mineral oil, white petrolatum, polyoxyl 20 cetostearyl ether, potassium citrate (monohydrate), propylene glycol, purified water, sorbitan monolaurate, and phenoxyethanol as a preservative. The can is pressurized with a hydrocarbon (propane/butane) propellant.

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

Issued 08/2011

Manufactured for
Stiefel Laboratories, Inc.
Research Triangle Park, NC 27709

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VDS:3PIL



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