HIGHLIGHTS OF PRESCRIBING INFORMATION

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

SORILUX™ (calcipotriene) Foam, 0.005%
For topical use

Initial U.S. Approval: 1993

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

- SORILUX Foam is a vitamin D analog indicated for the topical treatment of plaque psoriasis in patients aged 18 years and older. (1)

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

- For topical use only; not for oral, ophthalmic, or intravaginal use. (2)
- Apply twice daily. (2)

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

- 0.005%, foam. (3)

----------CONTRAINDICATIONS----------

- Do not use in patients with known hypercalcemia. (4)

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

- Contents are flammable. Instruct the patient to avoid fire, flame, and/or smoking during and immediately following application. (5.1)
- If elevation of serum calcium should occur, instruct patients to discontinue treatment until normal calcium levels are restored. (5.2)
- Instruct the patient to avoid excessive exposure of the treated areas to natural or artificial sunlight. (5.3)

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

- Adverse events reported in greater than 1% of subjects and in a higher rate in subjects treated with SORILUX Foam compared to vehicle were limited to erythema. (6.1)

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.

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

Revised: 10/2010

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SORILUX Foam is indicated for the topical treatment of plaque psoriasis in patients aged 18 years and older.

2 DOSAGE AND ADMINISTRATION

For topical use only. SORILUX Foam is not for oral, ophthalmic, or intravaginal use.

Apply a thin layer of SORILUX Foam twice daily to the affected areas and rub in gently and completely.

3 DOSAGE FORMS AND STRENGTHS

0.005%, white foam

4 CONTRAINDICATIONS

SORILUX Foam should not be used by patients with known hypercalcemia.

5 WARNINGS AND PRECAUTIONS

5.1 Flammability

The propellant in SORILUX is flammable. Instruct the patient to avoid fire, flame, and/or smoking during and immediately following application.

5.2 Effects on Calcium Metabolism

Transient, rapidly reversible elevation of serum calcium has occurred with use of calcipotriene. If elevation in serum calcium outside the normal range should occur, discontinue treatment until normal calcium levels are restored.

5.3 Ultraviolet Light Exposure

Instruct the patient to avoid excessive exposure of the treated areas to either natural or artificial sunlight, including tanning booths and sun lamps. Physicians may wish to limit or avoid use of phototherapy in patients who use SORILUX Foam. *[See Nonclinical Toxicology (13.1).]*

5.4 Unevaluated Uses

SORILUX Foam has not been evaluated in patients with erythrodermic, exfoliative, or pustular psoriasis.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

SORILUX Foam was studied in three-vehicle controlled trials. Seven hundred and thirty one subjects with plaque psoriasis, including 473 exposed to SORILUX Foam were treated twice daily for 8 weeks.

Adverse events reported in greater than 1% of subjects and in a higher rate in subjects treated with SORILUX Foam compared to vehicle were limited to erythema.

7 DRUG INTERACTIONS

No drug interaction studies were conducted with SORILUX Foam.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects, Pregnancy Category C:

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

Studies of teratogenicity were done by the oral route where bioavailability is expected to be approximately 40-60% of the administered dose. Increased rabbit maternal and fetal toxicity was noted at 12 mcg/kg/day (132 mcg/m^2/day). Rabbits administered 36 mcg/kg/day (396 mcg/m^2/day) resulted in fetuses with a significant increase in the incidences of incomplete ossification of pubic bones and forelimb phalanges. In a rat study, doses of 54 mcg/kg/day (318 mcg/m^2/day) resulted in a significantly higher incidence of skeletal abnormalities consisting primarily of enlarged fontanelles and extra ribs. The enlarged fontanelles are most likely due to calcipotriene's effect upon calcium metabolism. The maternal and fetal no-effect exposures in the rat (43.2 mcg/m^2/day) and rabbit (17.6 mcg/m^2/day) studies are approximately equal to the expected human systemic exposure level (18.5 mcg/m^2/day) from dermal application.

8.3 Nursing Mothers

It is not known whether calcipotriene is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORILUX Foam is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness of SORILUX Foam in pediatric patients less than 18 years of age have not been established.

8.5 Geriatric Use

Clinical studies of SORILUX Foam did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

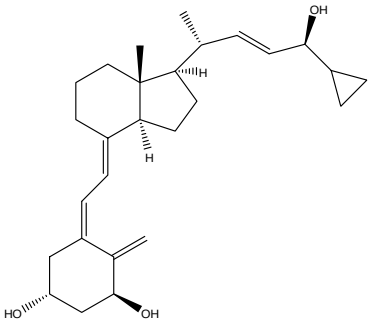
10 OVERDOSAGE

Topically applied calcipotriene can be absorbed in sufficient amounts to produce systemic effects. Elevated serum calcium has been observed with use of topical calcipotriene. *[See Warnings and Precautions (5.2).]*

11 DESCRIPTION

SORILUX contains the compound calcipotriene, a synthetic vitamin D_3 analog, for topical dermatological use.

Chemically, calcipotriene is (5Z,7E,22E,24S)-24-cyclopropyl-9,10-secochola-5,7,10(19), 22-tetraene-1α,3β,24-triol. The structural formula is represented below:



Molecular Formula: $C_{27}H_{40}O_3$ Molecular Weight: 412.6

Calcipotriene is a white or off-white crystalline substance. SORILUX Foam contains calcipotriene 50 mcg/g in an aqueous-based emulsion foam vehicle consisting of cetyl alcohol, dibasic sodium phosphate, edetate disodium, isopropyl myristate, light mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, stearyl alcohol, dl-α-tocopherol, and white petrolatum. SORILUX Foam is dispensed from an aluminum can pressurized with a hydrocarbon (propane/n-butane/isobutane) propellant.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Calcipotriene is a synthetic vitamin D_3 analog that has a similar receptor binding affinity as natural vitamin D_3. However, the exact mechanism of action contributing to the clinical efficacy in the treatment of psoriasis is unknown.

12.2 Pharmacodynamics

The pharmacodynamics of SORILUX Foam are unknown.

12.3 Pharmacokinetics

The systemic absorption of calcipotriene in psoriatic subjects was evaluated at steady state following application of SORILUX Foam or calcipotriene ointment. In the SORILUX Foam treatment group, 15 out of 16 subjects showed calcipotriene plasma concentrations below the limit of quantitation (10 pg/mL), while in the calcipotriene ointment treated group, 5 out of 16 subjects had measurable calcipotriene plasma concentrations at various time points. All measurable plasma calcipotriene concentrations were below 25 pg/mL.

The systemic disposition of calcipotriene is expected to be similar to that of the naturally occurring vitamin D. Absorbed calcipotriene is known to be converted to inactive metabolites within 24 hours of application and the metabolism occurs via a similar pathway to the natural hormone.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Calcipotriene topically administered to mice for up to 24 months at dose levels of 3, 10, or 30 mcg /kg/day (corresponding to 9, 30, or 90 mcg /m^2/day) showed no significant changes in tumor incidence when compared to controls. In a study in which albino hairless mice were exposed to both UVR and topically applied calcipotriene, a reduction in the time required for UVR to induce the formation of skin tumors was observed (statistically significant in males only), suggesting that calcipotriene may enhance the effect of UVR to induce skin tumors. *[See Warnings and Precautions (5.3).]*

The genotoxic potential of calcipotriene was evaluated in an Ames assay, a mouse lymphoma TK locus assay, a human lymphocyte chromosome aberration assay, and a mouse micronucleus assay. All assay results were negative.

Studies in rats at doses up to 54 mcg /kg/day (318 mcg /m^2/day) of calcipotriene indicated no impairment of fertility or general reproductive performance.

14 CLINICAL STUDIES

In two multi-center, randomized, double-blind, vehicle-controlled clinical studies a total of 659 subjects with psoriasis were randomized 2:1 to SORILUX Foam or vehicle; subjects applied the assigned medication twice daily for 8 weeks. Baseline disease severity was graded using a 5-point Investigator Static Global Assessment scale (ISGA), on which subjects scored either “mild” or “moderate” as shown in Table 1.

Table 1: Investigator Static Global Assessment (ISGA) Scale

Disease Severity	Grade	Definition
clear	0	No evidence of scaling, erythema, or plaque thickness
almost clear	1	Occasional fine scale, faint erythema, and barely perceptible plaque thickness
mild	2	Fine scale with light coloration and mild plaque elevation
moderate	3	Coarse scale with moderate red coloration and moderate plaque thickness
severe	4	Thick tenacious scale with deep coloration and severe plaque thickness

Efficacy evaluation was carried out at Week 8 with treatment success being defined as a score of “clear” (grade 0) or “almost clear” (grade 1) and at least 2 grade improvement from the baseline score. Approximately 30% of enrolled subjects were graded as “mild” on the ISGA scale. The study population ranged in age from 12 to 89 years with 10 subjects less than 18 years of age at baseline. The subjects were 54% male and 88% Caucasian. Table 2 presents the efficacy results for each study.

Table 2: Number and Percent of Subjects Achieving Success at Week 8 in Each Study

	Study 1		**Study 2**	
	SORILUX Foam N=223	**Vehicle Foam N=113**	**SORILUX Foam N= 214**	**Vehicle Foam N=109**
Number (%) of Subjects with Treatment Success	31 (14%)	8 (7%)	58 (27%)	17 (16%)

In one study, subjects graded as “mild” at baseline showed a greater response to vehicle than SORILUX Foam.

Table 3 presents the success rates by disease severity at baseline for each study.

Table 3: Number and Percent of Subjects Achieving Success by Baseline ISGA Score and by Study

	Study 1		**Study 2**	
ISGA scores at baseline	**SORILUX Foam (N=223)**	**Vehicle Foam (N=113)**	**SORILUX Foam (N=214)**	**Vehicle Foam (N=109)**
mild	2/73 (2.7%)	3/34 (8.8%)	8/56 (14.3%)	4/31 (12.9%)
moderate	29/150 (19.3%)	5/79 (6.3%)	50/158 (31.6%)	13/78 (16.7%)

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

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

SORILUX (calcipotriene) Foam, 0.005%, is supplied as follows:

60 g aluminum can	NDC 0145-2130-06
120 g aluminum can	NDC 0145-2130-07

16.2 Storage and Handling

- Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F).
- *FLAMMABLE. AVOID FIRE, FLAME, OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.* Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C).
- Avoid contact with eyes.
- Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

[See FDA-Approved Patient Labeling (Patient Information)]

The patient should be instructed as follows:

- Do not place SORILUX Foam in the refrigerator or freezer.
- Avoid excessive exposure of the treated areas to either natural or artificial sunlight, including tanning beds and sun lamps.
- If SORILUX Foam gets in or near their eyes, to rinse thoroughly with water.
- Talk to their doctor if their skin does not improve after treatment with SORILUX Foam for 8 weeks.
- Wash their hands after applying SORILUX Foam unless their hands are the affected site.
- Avoid fire, flame, or smoking during and immediately following application since SORILUX Foam is flammable.

SOR:3PI

Patient Information

SORILUX (SOR-i-lux)
(calcipotriene)
Foam

Important: For skin use only. Do not get SORILUX Foam in your eyes, mouth, or vagina.

Read the Patient Information that comes with SORILUX 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 SORILUX Foam?

SORILUX Foam is a prescription medicine used on the skin (topical) to treat psoriasis in people 18 years and older.

It is not known if SORILUX Foam is safe and effective in people under 18 years old.

Who should not use SORILUX Foam?

Do not use SORILUX Foam if you have been told by your doctor that you have a high level of calcium in your blood (hypercalcemia).

What should I tell my doctor before using SORILUX Foam?

Before you use SORILUX Foam, tell your doctor if you:

- are getting light therapy for your psoriasis
- have any other medical conditions
- are pregnant or planning to become pregnant. It is not known if SORILUX Foam can harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding. It is not known if SORILUX Foam passes into breast milk. Do not apply SORILUX Foam to the chest area if you are breastfeeding a baby. This will help to prevent the baby from accidentally getting SORILUX Foam into their mouth.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

How should I use SORILUX Foam?

- Apply SORILUX Foam exactly as prescribed. SORILUX Foam is usually applied to the affected skin areas two times each day.
- SORILUX Foam is for use on the skin only. Do not get SORILUX Foam in your eyes, mouth or vagina.
- SORILUX Foam is flammable. Avoid fire, flame, or smoking during and right after you apply SORILUX Foam to your skin.
- Avoid excessive sunlight. Wear a hat and clothes that cover the treated areas of your skin if you have to be in sunlight.

Instructions for applying SORILUX Foam

1. Before applying SORILUX Foam for the first time, break the tiny plastic piece at the base of the can's rim by gently pushing back (away from the piece) on the nozzle. See Figure A.

Figure A: Break tiny plastic piece on SORILUX Foam can nozzle.

2. Shake the SORILUX Foam can before use. See Figure B.

Figure B: Shake SORILUX Foam can.

3. Turn the SORILUX Foam can upside down and press the nozzle. See Figure C.

Figure C: Turn SORILUX Foam can upside down and press nozzle.

4. Dispense a small amount of SORILUX Foam into the palm of your hand. See Figure D.

Figure D: Dispense SORILUX Foam into hand.

5. Use enough SORILUX Foam to cover the affected area with a thin layer. Gently rub the foam into the affected area until it disappears into the skin. See Figure E.

Figure E: Cover affected area with thin layer of SORILUX Foam. Rub foam gently into affected skin.

6. Avoid getting SORILUX Foam in or near the eyes, mouth, or vagina. Wash hands after applying SORILUX Foam (excluding affected areas of the hands).

What are the possible side effects of SORILUX Foam?

The most common side effects of SORILUX Foam are irritation, redness, and itching of the treated skin areas.

Tell your doctor if you have any side effect that bothers you or that does not go away.

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

Call your doctor for medical advice about side effects. You may report side effects to Stiefel Laboratories, Inc. at 1-888-784-3335 (STIEFEL) or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store SORILUX Foam?

- Store SORILUX Foam at room temperature, between 68°F to 77°F (20C° to 25°C).
- SORILUX Foam is flammable. Keep the can away from all sources of fire and heat.
- Do not spray SORILUX Foam near fire or direct heat. Never throw the can into a fire, even if the can is empty.
- Do not puncture the SORILUX Foam can.

Keep SORILUX Foam and all medicines out of the reach of children.

General Information about SORILUX Foam

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use SORILUX Foam for a condition for which it was not prescribed. Do not give SORILUX Foam to other people even if they have the same symptoms that you have. It may harm them.

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

What are the ingredients of SORILUX Foam?

Active ingredient: calcipotriene

Inactive Ingredients: cetyl alcohol, dibasic sodium phosphate, edetate disodium, isopropyl myristate, light mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, purified water, stearyl alcohol, dl-α-tocopherol, and white petrolatum. The foam is dispensed from an aluminum can pressurized with a hydrocarbon (propane/n-butane/isobutane) propellant.

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

Issued: April/2011

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

Manufactured by:
DPT Laboratories, Ltd.
307 E. Josephine Street
San Antonio, TX 78215

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SORILUX is a trademark of Stiefel Laboratories, Inc.

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