

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

OLUX-E (clobetasol propionate) Foam, 0.05%

For topical use

Initial U.S. Approval: 1985

INDICATIONS AND USAGE

- OLUX-E Foam is a corticosteroid indicated for the treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 12 years and older. (1.1)

Limitations of Use

- Avoid face, axillae, and groin. (1.2)
- Avoid use if skin atrophy is present at the treatment site. (1.2)

DOSAGE AND ADMINISTRATION

OLUX-E Foam is not for oral, ophthalmic, or intravaginal use. (2)

Apply OLUX-E Foam to the affected area(s) twice daily, morning and evening, for up to 2 consecutive weeks. The maximum weekly dose should not exceed 50 g. (2)

DOSAGE FORMS AND STRENGTHS

Foam, 0.05%. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS and PRECAUTIONS

- OLUX-E Foam has been shown to suppress the HPA axis. Systemic absorption of OLUX-E Foam may produce reversible HPA axis suppression, Cushing’s syndrome, hyperglycemia, and unmask latent diabetes. (5.1)
- Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. (5.1)
- Modify use should HPA axis suppression develop. (5.1)
- High potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, and liver failure may predispose patients to HPA axis suppression. (5.1)
- Pediatric patients may be more susceptible to systemic toxicity when treated with topical corticosteroids. (5.1, 8.4)
- The propellant in OLUX-E Foam is flammable. Avoid fire, flame, or smoking during and immediately following application. (5.4)

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥1%) are application site atrophy and application site reaction. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Stiefel Laboratories, Inc. at 1-888-784-3335 (1-888-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: 04/2013

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

- 1.1 Indication
- 1.2 Limitations of Use

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Effects on Endocrine System
- 5.2 Local Adverse Reactions with Topical Corticosteroids
- 5.3 Concomitant Skin Infections
- 5.4 Flammable Contents

6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 6.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
- 8.3 Nursing Mothers

8.4 Pediatric Use

8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- 12.1 Mechanism of Action
- 12.2 Pharmacodynamics
- 12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

- 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

- 16.1 How Supplied
- 16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

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

1 FULL PRESCRIBING INFORMATION

2 1 INDICATIONS AND USAGE

3 1.1 Indication

4 OLUX-E[®] Foam is indicated for the treatment of inflammatory and pruritic
5 manifestations of corticosteroid-responsive dermatoses in patients 12 years and older.

6 1.2 Limitations of Use

- 7 • OLUX-E Foam should not be applied to the face, axillae, or groin.
- 8 • OLUX-E Foam should not be used if there is skin atrophy at the treatment site.
- 9 • Treatment should be limited to 2 consecutive weeks and patients should not use greater than
10 50 grams or more than 21 capfuls per week.

11

12 **2 DOSAGE AND ADMINISTRATION**

13 OLUX-E Foam is not for oral, ophthalmic, or intravaginal use.

14 Apply a thin layer of OLUX-E Foam to the affected area(s) twice daily, morning and
15 evening, for up to 2 consecutive weeks; therapy should be discontinued when control has been
16 achieved. The maximum weekly dose should not exceed 50 g or an amount greater than 21
17 capfuls per week. For proper dispensing of foam, shake the can, hold it upside down, and depress
18 the actuator. Dispense a small amount of foam (about a capful) and gently massage the
19 medication into the affected areas (excluding the face, groin, and axillae) until the foam is
20 absorbed. Avoid contact with the eyes.

21 **3 DOSAGE FORMS AND STRENGTHS**

22 Foam, 0.05%. Each gram of OLUX E Foam contains 0.5 mg of clobetasol propionate in a
23 white to off-white petrolatum-based emulsion aerosol foam.

24 **4 CONTRAINDICATIONS**

25 None.

26 **5 WARNINGS AND PRECAUTIONS**

27 **5.1 Effects on Endocrine System**

28 OLUX-E Foam has been shown to suppress the hypothalamic-pituitary-adrenal (HPA)
29 axis.

30 Systemic absorption of OLUX-E has caused reversible HPA axis suppression with the
31 potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon
32 withdrawal of the topical corticosteroid. Use of OLUX-E Foam for longer than 2 weeks may
33 suppress the immune system [*see Nonclinical Toxicology (13.1)*].

34 In a trial including 37 subjects 12 years and older with at least 30% body surface area
35 (BSA), adrenal suppression was identified in 6 out of 37 subjects (16.2%) after 2 weeks of
36 treatment with OLUX-E [*see Clinical Pharmacology (12.2)*].

37 Because of the potential for systemic absorption, use of OLUX-E may require that
38 patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient
39 using a topical corticosteroid to HPA axis suppression include the use of more potent steroids,
40 use over large surface areas, use over prolonged periods, use under occlusion, use on an altered
41 skin barrier, and use in patients with liver failure.

42 An adrenocorticotrophic hormone (ACTH) stimulation test may be helpful in evaluating
43 patients for HPA axis suppression. If HPA axis suppression is documented, an attempt should be
44 made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a
45 less potent steroid. Manifestations of adrenal insufficiency may require systemic corticosteroids.
46 Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical
47 corticosteroids.

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

50 Use of more than 1 corticosteroid-containing product at the same time may increase the
51 total systemic corticosteroid exposure.

52 Pediatric patients may be more susceptible to systemic toxicity from equivalent doses
53 because of their larger skin surface-to-body mass ratios [*see Use in Specific Populations (8.4)*].

54 **5.2 Local Adverse Reactions with Topical Corticosteroids**

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

60 Allergic contact dermatitis to any component of topical corticosteroids is usually
61 diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic
62 contact dermatitis can be confirmed by patch testing.

63 If irritation develops, treatment with OLUX-E Foam should be discontinued and
64 appropriate therapy instituted.

65 **5.3 Concomitant Skin Infections**

66 Concomitant skin infections should be treated with an appropriate antimicrobial agent. If
67 the infection persists, OLUX-E Foam should be discontinued until the infection has been
68 adequately treated.

69 **5.4 Flammable Contents**

70 The propellant in OLUX-E Foam is flammable. Avoid fire, flame, or smoking during and
71 immediately following application. Do not puncture and/or incinerate the containers. Do not
72 expose containers to heat and/or store at temperatures above 120°F (49°C).

73 **6 ADVERSE REACTIONS**

74 **6.1 Clinical Trials Experience**

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

78 In controlled clinical trials involving 821 subjects exposed to OLUX-E Foam and vehicle
79 foam, the pooled incidence of local adverse reactions in trials for atopic dermatitis and psoriasis
80 with OLUX-E Foam was 1.9% for application site atrophy and 1.6% for application site reaction.
81 Most local adverse events were rated as mild to moderate and they were not affected by age,
82 race, or gender.

83 The following additional local adverse reactions have been reported with topical
84 corticosteroids: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic
85 contact dermatitis, secondary infection, irritation, striae, and miliaria. They may occur more

86 frequently with the use of occlusive dressings and higher potency corticosteroids, such as
87 clobetasol propionate.

88 Cushing's syndrome has been reported in infants and adults as a result of prolonged use
89 of topical clobetasol propionate formulations.

90 **6.2 Postmarketing Experience**

91 Because these reactions are reported voluntarily from a population of uncertain size, it is
92 not always possible to reliably estimate their frequency or establish a causal relationship to drug
93 exposure.

94 The following adverse reactions have been identified during post-approval use of
95 clobetasol formulations: erythema, pruritus, burning, alopecia, and dryness.

96 **8 USE IN SPECIFIC POPULATIONS**

97 **8.1 Pregnancy**

98 Teratogenic Effects. Pregnancy Category C.

99 There are no adequate and well-controlled studies of OLUX-E Foam in pregnant women.
100 OLUX-E Foam should be used during pregnancy only if the potential benefit justifies the
101 potential risk to the fetus.

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

105 Clobetasol propionate has not been tested for teratogenicity when applied topically;
106 however, it is absorbed percutaneously, and when administered subcutaneously, it was a
107 significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater
108 teratogenic potential than steroids that are less potent.

109 Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the
110 highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested down to 0.03 mg/kg.
111 These doses are approximately 1.4 and 0.04 times, respectively, the human topical dose of
112 OLUX-E Foam based on body surface area comparisons. Abnormalities seen included cleft
113 palate and skeletal abnormalities.

114 In rabbits, clobetasol propionate was teratogenic at doses of 0.003 and 0.01 mg/kg. These
115 doses are approximately 0.02 and 0.05 times, respectively, the human topical dose of OLUX-E
116 Foam based on body surface area comparisons. Abnormalities seen included cleft palate,
117 cranioschisis, and other skeletal abnormalities.

118 **8.3 Nursing Mothers**

119 Systemically administered corticosteroids appear in human milk and could suppress
120 growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It
121 is not known whether topical administration of corticosteroids could result in sufficient systemic
122 absorption to produce detectable quantities in breast milk. Because many drugs are excreted in
123 human milk, caution should be exercised when OLUX-E Foam is administered to a nursing
124 woman.

125 If used during lactation, OLUX-E Foam should not be applied on the chest to avoid
126 accidental ingestion by the infant.

127 **8.4 Pediatric Use**

128 Use in pediatric patients younger than 12 years is not recommended because of the risk of
129 HPA axis suppression.

130 After 2 weeks of twice-daily treatment with OLUX-E Foam, 7 of 15 subjects (47%) aged
131 6 to 11 years demonstrated HPA axis suppression. The laboratory suppression was transient; in
132 all subjects serum cortisol levels returned to normal when tested 4 weeks post-treatment.

133 In 92 subjects aged 12 to 17 years, safety was similar to that observed in the adult
134 population. Based on these data, no adjustment of dosage of OLUX-E Foam in adolescent
135 patients aged 12 to 17 years is warranted [*see Warnings and Precautions (5.1)*].

136 Because of a higher ratio of skin surface area to body mass, pediatric patients are at a
137 greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated
138 with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during
139 and/or after withdrawal of treatment.

140 HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight
141 gain, and intracranial hypertension have been reported in children receiving topical
142 corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol
143 levels and an absence of response to ACTH stimulation. Manifestations of intracranial
144 hypertension include bulging fontanelles (in infants), headaches, and bilateral papilledema.
145 Administration of topical corticosteroids to children should be limited to the least amount
146 compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere
147 with the growth and development of children.

148 Adverse effects, including striae, have been reported with inappropriate use of topical
149 corticosteroids in infants and children.

150 **8.5 Geriatric Use**

151 A limited number of subjects aged 65 years or older have been treated with OLUX-E
152 Foam (n = 58) in US clinical trials. While the number of subjects is too small to permit separate
153 analysis of efficacy and safety, the adverse reactions reported in this population were similar to
154 those reported by younger subjects. Based on available data, no adjustment of dosage of OLUX-
155 E Foam in geriatric patients is warranted.

156 **10 OVERDOSAGE**

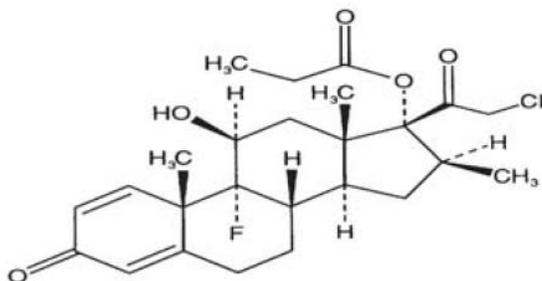
157 Topically applied OLUX-E Foam can be absorbed in sufficient amounts to produce
158 systemic effects.

159 **11 DESCRIPTION**

160 OLUX-E (clobetasol propionate) Foam, 0.05% is a white to off-white petrolatum-based
161 emulsion aerosol foam containing the active ingredient clobetasol propionate USP, a synthetic
162 corticosteroid for topical dermatologic use. Clobetasol, an analog of prednisolone, has a high
163 degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

164 Clobetasol propionate is 21-chloro-9-fluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-
165 diene-3,20-dione 17-propionate, with the empirical formula C₂₅H₃₂ClFO₅, and a molecular
166 weight of 466.97.

167 The following is the chemical structure:



Clobetasol Propionate, USP

168 Clobetasol propionate is a white to cream-colored crystalline powder, practically
169 insoluble in water.

171 Each gram of OLUX-E Foam contains 0.5 mg clobetasol propionate, USP. The foam also
172 contains anhydrous citric acid, cetyl alcohol, cyclomethicone, isopropyl myristate, light mineral
173 oil, polyoxyl 20 cetostearyl ether, potassium citrate monohydrate, propylene glycol, purified
174 water, sorbitan monolaurate, white petrolatum, and phenoxyethanol as a preservative.

175 OLUX-E Foam is dispensed from an aluminum can pressurized with a hydrocarbon
176 (propane/butane) propellant.

177 **12 CLINICAL PHARMACOLOGY**

178 **12.1 Mechanism of Action**

179 Corticosteroids play a role in cellular signaling, immune function, inflammation, and
180 protein regulation; however, the precise mechanism of action in corticosteroid-responsive
181 dermatoses is unknown.

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

184 **12.2 Pharmacodynamics**

185 In a trial evaluating the potential for HPA axis suppression using the cosyntropin
186 stimulation test, OLUX-E Foam demonstrated reversible adrenal suppression after 2 weeks of
187 twice-daily use in subjects with atopic dermatitis of at least 30% body surface area (BSA). The
188 proportion of subjects aged 12 years and older demonstrating HPA axis suppression was 16.2%
189 (6 out of 37). In this trial HPA axis suppression was defined as serum cortisol level \leq 18 mcg/dL
190 30 minutes post cosyntropin stimulation. The laboratory suppression was transient; in all subjects
191 serum cortisol levels returned to normal when tested 4 weeks post treatment [*see Warnings and*
192 *Precautions (5.1), Use in Specific Populations (8.4)].*

193 **12.3 Pharmacokinetics**

194 Topical corticosteroids can be absorbed from intact healthy skin. The extent of
195 percutaneous absorption of topical corticosteroids is determined by many factors, including the

196 product formulation and the integrity of the epidermal barrier. Occlusion, inflammation, and/or
197 other disease processes in the skin may increase percutaneous absorption. The use of
198 pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids may
199 be necessary due to the fact that circulating levels are often below the level of detection. Once
200 absorbed through the skin, topical corticosteroids are metabolized primarily in the liver and are
201 then excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the
202 bile.

203 Following twice-daily application of OLUX-E Foam for 1 week to 32 adult subjects with
204 mild to moderate plaque-type psoriasis, mean peak plasma concentrations (\pm SD) of 59 ± 36
205 pg/mL of clobetasol were observed at around 5 hours post dose on Day 8.

206 **13 NONCLINICAL TOXICOLOGY**

207 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

208 Long-term animal studies have not been performed to evaluate the carcinogenic potential
209 of OLUX-E Foam or clobetasol propionate.

210 In a 90-day repeat-dose toxicity study in rats, topical administration of OLUX-E Foam at
211 dose concentrations from 0.001% to 0.1% or from 0.03 to 0.3 mg/kg/day of clobetasol
212 propionate resulted in a toxicity profile consistent with long-term exposure to corticosteroids
213 including adrenal atrophy, histopathological changes in several organs systems indicative of
214 severe immune suppression, and opportunistic fungal and bacterial infections. A no observable
215 adverse effect level (NOAEL) could not be determined in this study. Although the clinical
216 relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related
217 immune suppression may increase the risk of infection and possibly the risk for carcinogenesis.

218 Topical doses of 0% (foam vehicle), 0.001%, 0.01%, and 0.05% clobetasol propionate
219 foam were evaluated in a 52-week dermal photocarcinogenicity study (40 weeks of treatment
220 followed by 12 weeks of observation) conducted in hairless albino mice with concurrent
221 exposure to low-level ultraviolet radiation. Topical treatment with increasing concentrations of
222 clobetasol propionate foam did not have an adverse effect in this study. The results of this study
223 suggest that topical treatment with OLUX-E Foam would not enhance photocarcinogenesis.

224 Clobetasol propionate was non-mutagenic in 4 different test systems: the Ames test, the
225 mouse lymphoma test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B
226 WP2 fluctuation test. In the in vivo mouse micronucleus test, a positive finding was observed at
227 24 hours, but not at 48 hours, following oral administration at a dose of 2,000 mg/kg.

228 Studies in the rat following subcutaneous administration of clobetasol propionate at
229 dosage levels up to 0.05 mg/kg per day revealed that the females exhibited an increase in the
230 number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

231 **14 CLINICAL STUDIES**

232 In a randomized trial of subjects 12 years and older with moderate to severe atopic
233 dermatitis, 251 subjects were treated with OLUX-E Foam and 126 subjects were treated with
234 vehicle foam. Subjects were treated twice daily for 2 weeks. At the end of treatment, 131 of 251

235 subjects (52%) treated with OLUX-E Foam compared with 18 of 126 subjects (14%) treated with
236 vehicle foam achieved treatment success. Treatment success was defined by an Investigator's
237 Static Global Assessment (ISGA) score of clear (0) or almost clear (1) with at least 2 grades
238 improvement from baseline, and scores of absent or minimal (0 or 1) for erythema and
239 induration/papulation.

240 In an additional randomized trial of subjects 12 years and older with mild to moderate
241 plaque-type psoriasis, 253 subjects were treated with OLUX-E Foam and 123 subjects were
242 treated with vehicle foam. Subjects were treated twice daily for 2 weeks. At the end of treatment,
243 41 of 253 subjects (16%) treated with OLUX-E Foam compared with 5 of 123 subjects (4%)
244 treated with vehicle foam achieved treatment success. Treatment success was defined by an
245 ISGA score of clear (0) or almost clear (1) with at least 2 grades improvement from baseline,
246 scores of none or faint/minimal (0 or 1) for erythema and scaling, and a score of none (0) for
247 plaque thickness.

248 **16 HOW SUPPLIED/STORAGE AND HANDLING**

249 **16.1 How Supplied**

250 OLUX-E (clobetasol propionate) Foam, 0.05% is a white to off-white aerosol foam
251 supplied as follows:

- 252 • 50 g aluminum can NDC 63032-101-50
- 253 • 100 g aluminum can NDC 63032-101-00

254 **16.2 Storage and Handling**

255 Store at controlled room temperature 68°F to 77°F (20°C to 25°C) with excursions
256 permitted between 59°F to 86°F (15°C to 30°C).

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

259 Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at
260 temperatures above 120°F (49°C).

261 Keep out of reach of children.

262 **17 PATIENT COUNSELING INFORMATION**

263 *See FDA-approved patient labeling (Patient Information)*

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

- 266 • This medication is to be used as directed by the physician. It is for external use only. Unless
267 directed by the prescriber, it should not be used on the face or in skin-fold areas, such as the
268 underarms or groin. Avoid contact with the eyes or other mucous membranes. Wash hands
269 after use.
- 270 • This medication should not be used for any disorder other than that for which it was
271 prescribed.
- 272 • The treated skin area should not be bandaged, wrapped, or otherwise covered so as to be
273 occlusive unless directed by the physician.

- 274 • Patients should report any signs of local or systemic adverse reactions to the physician.
- 275 • Patients should inform their physicians that they are using OLUX-E Foam if surgery is
- 276 contemplated.
- 277 • As with other corticosteroids, therapy should be discontinued when control is achieved. If no
- 278 improvement is seen within 2 weeks, contact the physician.
- 279 • Patients should not use more than 50 grams per week of OLUX-E Foam, or an amount
- 280 greater than 21 capfuls per week [see *Dosage and Administration (2)*].
- 281 • This medication is flammable; avoid heat, flame, or smoking when applying this product.

282

283 OLUX-E is a registered trademark of Stiefel Laboratories, Inc.

284

285 Manufactured for



286

287 Stiefel Laboratories, Inc.

288 Research Triangle Park, NC 27709

289

290 ©2013, Stiefel Laboratories, Inc.

291

292 OLE:PI

293

294 PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

295

296

PATIENT INFORMATION

297

298

299

300

**OLUX-E[®] (O-lux-E)
(clobetasol propionate)
Foam**

IMPORTANT: For skin use only. Do not get OLUX-E Foam in your eyes, mouth, or vagina.

301

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

305

306 **What is OLUX-E Foam?**

307 OLUX-E Foam is a prescription corticosteroid medicine used on the skin (topical) to
308 treat adults and children 12 years and older with certain skin conditions that cause
309 red, flaky, and itchy skin.

310

311 OLUX-E Foam should not be used:

- 312 • on your face, underarms, or groin area.
- 313 • if you have skin thinning (atrophy) at the treatment area.

314

315 You should not use OLUX-E Foam for longer than 2 weeks in a row.

316 You should not use more than 50 grams or 21 capfuls of OLUX-E Foam in 1 week.

317

318 **What should I tell my doctor before using OLUX-E Foam?**

319 **Before you use OLUX-E Foam, tell your doctor if you:**

- 320 • have had irritation or other skin reaction to a steroid medicine in the past.
- 321 • have a skin infection. You may need medicine to treat the skin infection before
322 using OLUX-E Foam.
- 323 • have diabetes.
- 324 • have adrenal gland problems.
- 325 • have liver problems.
- 326 • plan to have surgery.
- 327 • have any other medical condition.
- 328 • are pregnant or plan to become pregnant. It is not known if OLUX-E Foam will
329 harm your unborn baby. Talk to your doctor if you are pregnant or plan to
330 become pregnant.
- 331 • are breastfeeding or plan to breastfeed. It is not known if OLUX-E Foam passes
332 into your breast milk.

333

334 Do not apply OLUX-E Foam to your chest area if you are breastfeeding a baby. This
335 will help to prevent the baby from accidentally getting OLUX-E Foam into the baby's
336 mouth.

337

338 **Tell your doctor about all the medicine you take** including prescription and
339 non-prescription medicines, vitamins, and herbal supplements. Especially tell your
340 doctor if you take other corticosteroid medicines by mouth or use other products on
341 your skin that contain corticosteroids. Ask your doctor or pharmacist if you are not
342 sure.

343

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

346

347 **How should I use OLUX-E Foam?**

- 348 • See "What is OLUX-E Foam?"
- 349 • Use OLUX-E Foam exactly as your doctor tells you to use it. See the
- 350 "Instructions for applying OLUX-E Foam".
- 351 • This medicine is for use on the skin only. Do not get OLUX-E Foam in your eyes,
- 352 mouth, or vagina.
- 353 • Apply OLUX-E Foam 2 times each day, 1 time in the morning and 1 time at
- 354 night, or as directed by your doctor.
- 355 • Do not bandage or cover your treated area unless your doctor tells you to.
- 356 • Do not use OLUX-E Foam for longer than 2 weeks in a row.
- 357 • Talk to your doctor if your skin does not improve after 2 weeks of treatment
- 358 with OLUX-E Foam.
- 359 • See your doctor regularly to check your symptoms and side effects while taking
- 360 OLUX-E Foam.
- 361 • OLUX-E Foam is flammable. Avoid heat, flame, or smoking during and right after
- 362 using OLUX-E Foam.

363

364 **Instructions for applying OLUX-E Foam**

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

368



369

370

371

372

373

Figure A: Break tiny plastic piece on the nozzle of the can of OLUX-E Foam.

2. Shake the can of OLUX-E Foam before use.



Figure B: Shake the can of OLUX-E Foam.

374
375
376
377

3. Turn the can of OLUX-E Foam upside down and press the nozzle. See Figure C.



Figure C: Turn the can of OLUX-E Foam upside down and press nozzle.

378
379
380
381
382
383

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



Figure D: Dispense OLUX-E Foam into hand.

384
385
386
387
388

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



389
390 Figure E: Cover affected area with thin layer of OLUX-E Foam. Rub foam gently
391 into affected skin.

392
393 6. Avoid getting OLUX-E Foam in or near your mouth, eyes, or vagina; if contact
394 happens, rinse well with water. Wash your hands well after applying OLUX-E Foam
395 (excluding affected areas of hands).

396
397 **What should I avoid while using OLUX-E Foam?**

398 OLUX-E Foam is flammable. Avoid heat, flame, or smoking during and right after
399 you apply it to your skin.

400
401 If you are taking other corticosteroid medicines, either by mouth or injection, your
402 doctor may advise you to stop taking them once you begin using OLUX-E Foam.

403
404 **What are the possible side effects of OLUX-E Foam?**

405 OLUX-E Foam may cause serious side effects, including:

406 • **Symptoms of a disorder where the adrenal gland does not make enough**
407 **of certain hormones (adrenal insufficiency) during treatment or after**
408 **stopping treatment.** Your doctor may do blood tests to check you for adrenal
409 insufficiency while you are using OLUX-E Foam. Tell your doctor if you have any
410 of these persistent symptoms of adrenal insufficiency:

- 411
- tiredness that worsens and does not go away
 - muscle weakness
 - loss of appetite
 - nausea or vomiting
 - dizziness or fainting
 - irritability and depression
 - weight loss

412
413 • **Cushing's syndrome, when the body is exposed to too much of the**
414 **hormone cortisol.** Your doctor may do tests to check for this. Symptoms can
415 include:

- weight gain, especially around
- slow healing of cuts, insect bites, and

your upper back and midsection

- tiredness and muscle weakness
- depression, anxiety, and irritability
- roundness of your face (moon face)
- new or worsening high blood pressure

416

417 • **high blood sugar (hyperglycemia) or diabetes mellitus that has not been**
418 **diagnosed can happen with treatment.** Your doctor may do tests to check
419 you for this.

420 • **skin problems, including reactions where the medicine is applied, skin**
421 **infections, and allergic reactions** (allergic contact dermatitis). Tell your
422 doctor if you get any new skin problems.

423 • **effects on growth and weight in children.**

424

425 The most common side effects of OLUX-E Foam include:

- 426 • thinning of skin
- 427 • burning
- 428 • redness
- 429 • itching
- 430 • dryness

431

432 Tell your doctor if you have any reaction on your treated skin such as pain,
433 tenderness, swelling, or healing problems.

434

435 These are not all the side effects of OLUX-E Foam. Ask your doctor or pharmacist
436 for more information.

437

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

441

442 **How should I store OLUX-E Foam?**

- 443 • Store OLUX-E Foam at room temperature, between 68°F to 77°F (20°C to
444 25°C). OLUX-E Foam is flammable. Keep the can away from fire and heat.
- 445 • Do not pierce or burn the can of OLUX-E Foam.
- 446 • Keep out of reach of children.

447

448 **Keep OLUX-E Foam and all medicines out of the reach of children.**

449

450 **General information about OLUX-E Foam**

451

452 Medicines are sometimes prescribed for purposes other than those listed in Patient
453 Information leaflets. Do not use OLUX-E Foam for a condition for which it was not
454 prescribed. Do not give OLUX-E Foam to other people, even if they have the same
455 condition that you have. It may harm them.

456
457 This Patient Information leaflet summarizes the most important information about
458 OLUX-E Foam. If you would like more information, talk with your doctor. You can
459 ask your doctor or pharmacist for information about OLUX-E Foam that is written
460 for health professionals.

461
462 **What are the ingredients in OLUX-E Foam?**
463 **Active ingredient:** clobetasol propionate, USP, 0.05%
464 **Inactive Ingredients:** anhydrous citric acid, cetyl alcohol, cyclomethicone,
465 isopropyl myristate, light mineral oil, polyoxyl 20 cetostearyl ether, potassium
466 citrate monohydrate, propylene glycol, purified water, sorbitan monolaurate, white
467 petrolatum, and phenoxyethanol as a preservative; pressurized with a hydrocarbon
468 (propane/butane) propellant.

469
470 This Patient Information has been approved by the U.S. Food and Drug
471 Administration.

472
473 OLUX-E is a registered trademark of Stiefel Laboratories, Inc.

474
475 Manufactured for



476
477 Stiefel Laboratories, Inc.
478 Research Triangle Park, NC 27709

479
480 ©2013, Stiefel Laboratories, Inc.

481
482 Revised: 04/2013
483 OLE:PIL