

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

OLUX (clobetasol propionate) Foam, 0.05% for topical use
Initial U.S. Approval: 1985

INDICATIONS AND USAGE

OLUX Foam is a corticosteroid indicated for treatment of moderate to severe plaque psoriasis of the scalp and mild to moderate plaque psoriasis of non-scalp regions of the body excluding the face and intertriginous areas in patients 12 years and older. (1)

DOSAGE AND ADMINISTRATION

- Apply a thin layer to the affected skin areas twice daily. (2)
- Limit treatment to 2 consecutive weeks. (2)
- Do not use more than 50 grams per week or more than 21 capfuls per week. (2)
- Discontinue therapy when control is achieved. (2)
- Do not use with occlusive dressings unless directed by physician. (2)
- Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site. (2)

DOSAGE FORMS AND STRENGTHS

- Foam, 0.05% (3)

CONTRAINDICATIONS

- None. (4)

WARNINGS AND PRECAUTIONS

- OLUX Foam can cause reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency during and after withdrawal of treatment. Risk factors include the use of high-potency topical corticosteroid, use over a large surface area or to areas under occlusion, prolonged use, altered skin barrier, liver failure, and use in pediatric patients. Modify use should HPA axis suppression develop. (5.1, 8.4)
- OLUX Foam is flammable. Avoid fire, flame, or smoking during and immediately following application. (5.3)

ADVERSE REACTIONS

Most common adverse reactions (≥ 4%) are application site burning and other application site reactions. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Prestium Pharma, Inc. at 1-866-897-5002 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Revised: 04/2014

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43 **FULL PRESCRIBING INFORMATION**

44
45
46 **1 INDICATIONS AND USAGE**

47 OLUX Foam is a corticosteroid indicated for treatment of moderate to severe plaque
48 psoriasis of the scalp and mild to moderate plaque psoriasis of non-scalp regions of the
49 body excluding the face and intertriginous areas in patients 12 years and older.

50
51
52 **2 DOSAGE AND ADMINISTRATION**

53 Apply a thin layer of OLUX Foam to the affected skin areas twice daily.

54
55 OLUX Foam is a super-high-potency topical corticosteroid; therefore treatment should
56 be limited to 2 consecutive weeks and patients should not use greater than 50 grams
57 per week or more than 21 capfuls per week because of the potential for the drug to
58 suppress the hypothalamic-pituitary-adrenal (HPA) axis.

59
60 Therapy should be discontinued when control is achieved.

61
62 OLUX Foam should not be used with occlusive dressings unless directed by a
63 physician.

64
65 OLUX Foam is for topical use only. It is not for oral, ophthalmic, or intravaginal use.

66
67 Avoid use on the face, groin, or axillae, or if skin atrophy is present at the treatment site.

68
69
70 **3 DOSAGE FORMS AND STRENGTHS**

71 Foam, 0.05%. Each gram of OLUX Foam contains 0.5 mg of clobetasol propionate in a
72 white aerosol foam.

73
74
75 **4 CONTRAINDICATIONS**

76 | None.

77
78
79 **5 WARNINGS AND PRECAUTIONS**

80
81 **5.1 Effects on Endocrine System**

82 OLUX Foam can cause reversible hypothalamic-pituitary-adrenal (HPA) axis
83 suppression with the potential for glucocorticosteroid insufficiency. This may occur
84 during treatment or after withdrawal of treatment. Factors that predispose a patient to
85 HPA axis suppression include the use of high-potency steroids, large treatment surface
86 areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and
87 young age. Evaluation for HPA axis suppression may be done by using the
88 adrenocorticotrophic hormone (ACTH) stimulation test.

89
90 In a trial evaluating the effects of OLUX Foam on the HPA axis, 13 subjects applied
91 OLUX Foam to at least 20% of involved body surface area for 14 days. HPA axis

92 suppression was identified in 5 out of 13 subjects (38%) [see *Clinical Pharmacology*
93 (12.2)].

94
95 If HPA axis suppression is documented, gradually withdraw the drug, reduce the
96 frequency of application, or substitute with a less potent corticosteroid.

97
98 Cushing's syndrome and hyperglycemia may also occur due to the systemic effects of
99 the topical corticosteroid. These complications are rare and generally occur after
100 prolonged exposure to excessively large doses, especially of high-potency topical
101 corticosteroids.

102
103 Pediatric patients may be more susceptible to systemic toxicity due to their larger skin
104 surface to body mass ratios [see *Use in Specific Populations* (8.4)].

105
106 **5.2 Allergic Contact Dermatitis**
107 Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure
108 to heal rather than noting a clinical exacerbation. Such an observation should be
109 corroborated with appropriate diagnostic patch testing.

110
111 **5.3 Flammable Contents**
112 OLUX Foam is flammable. Avoid fire, flame, or smoking during and immediately
113 following application.

114
115
116 **6 ADVERSE REACTIONS**

117
118 **6.1 Clinical Trials Experience**
119 Because clinical trials are conducted under widely varying conditions, adverse reaction
120 rates observed in the clinical trials of a drug cannot be directly compared to rates in the
121 clinical trials of another drug and may not reflect the rates observed in clinical practice.

122
123 In a controlled clinical trial involving 188 subjects with psoriasis of the scalp, there were
124 no localized scalp adverse reactions reported in the subjects treated with OLUX Foam.
125 In 2 controlled clinical trials with OLUX Foam in 360 subjects with psoriasis of non-
126 scalp regions, localized adverse events that occurred in the subjects treated with OLUX
127 Foam included application site burning (10%), application site dryness (<1%), and other
128 application site reactions (4%).

129
130 In larger controlled trials with other clobetasol propionate formulations, the most
131 frequently reported local adverse reactions have included burning, stinging, irritation,
132 pruritus, erythema, folliculitis, cracking and fissuring of the skin, numbness of the
133 fingers, skin atrophy, and telangiectasia (all less than 2%).

134

6.2 Postmarketing Experience

Because adverse 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.

Postmarketing reports for local adverse reactions to topical corticosteroids may also include: striae, itching, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and miliaria.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women. OLUX 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. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

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

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

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

8.3 Nursing Mothers

Systemically administered corticosteroids appear in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids can 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 OLUX Foam is administered to a nursing woman.

181 **8.4 Pediatric Use**

182 Safety and effectiveness of OLUX Foam in patients younger than 12 years of age have
183 not been established; therefore, use in children younger than 12 years is not
184 recommended.

185
186 Because of a higher ratio of skin surface area to body mass, pediatric patients are at a
187 greater risk than adults of systemic toxicity when they are treated with topical drugs.
188 They are, therefore, also at greater risk of adrenal insufficiency upon the use of topical
189 corticosteroids.

190
191 Rare systemic toxicities such as Cushing's syndrome, linear growth retardation, delayed
192 weight gain, and intracranial hypertension have been reported in pediatric patients
193 especially those with prolonged exposure to large doses of high potency topical
194 corticosteroids.

195
196 Local adverse reactions including striae have also been reported with use of topical
197 corticosteroids in pediatric patients.

198
199 Avoid use of OLUX Foam in the treatment of diaper dermatitis.

200
201 **8.5 Geriatric Use**

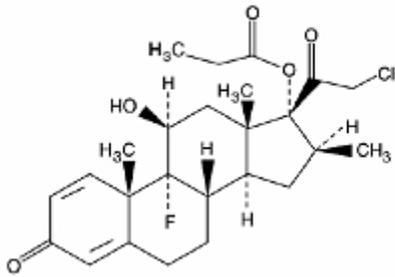
202 Clinical studies of OLUX Foam did not include sufficient numbers of subjects aged 65
203 and over to determine whether they respond differently from younger subjects. Other
204 reported clinical experience has not identified differences in responses between the
205 elderly and younger patients. In general, dose selection for an elderly patient should be
206 cautious, usually starting at the low end of the dosing range.

207
208
209 **11 DESCRIPTION**

210 OLUX (clobetasol propionate) Foam, 0.05%, is a white thermolabile hydroethanolic
211 aerosol foam containing the active ingredient, clobetasol propionate, USP, a synthetic
212 corticosteroid, for topical use. Clobetasol, an analog of prednisolone, has a high degree
213 of glucocorticoid activity and a slight degree of mineralocorticoid activity.

214
215 Clobetasol propionate is 21-chloro-9-fluoro-11 β ,17-dihydroxy-16 β -methylpregna-1,4-
216 diene-3,20-dione 17-propionate, with the empirical formula C₂₅H₃₂ClFO₅, a molecular
217 weight of 466.97.

219 The following is the chemical structure:
220



221
222 Clobetasol propionate is a white to cream-colored crystalline powder, practically
223 insoluble in water.

224
225 Each gram of OLUX Foam contains 0.5 mg clobetasol propionate, USP. The foam also
226 contains cetyl alcohol, citric acid, ethanol (60%), polysorbate 60, potassium citrate,
227 propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon
228 (propane/butane) propellant.

229
230

231 12 CLINICAL PHARMACOLOGY

232

233 12.1 Mechanism of Action

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

237

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

240

241 12.2 Pharmacodynamics

242 In a controlled pharmacokinetic trial, 5 of 13 subjects experienced reversible
243 suppression of the adrenals at any time during the 14 days of therapy with OLUX Foam
244 applied to at least 20% of involved body surface area. Of the 13 subjects studied, 1 of 9
245 with psoriasis was suppressed after 14 days and all 4 of the subjects with atopic
246 dermatitis had abnormal cortisol levels indicative of adrenal suppression at some time
247 after starting therapy with OLUX Foam (See Table 1 below).

248

249 **Table 1: Subjects With Reversible HPA Axis Suppression at Any Time During**
250 **Treatment**

Dermatosis	OLUX Foam
Psoriasis	1 of 9
Atopic Dermatitis ^a	4 of 4

251 ^a OLUX Foam is not indicated for non-scalp atopic dermatitis, as the safety and efficacy of OLUX Foam in non-scalp
252 atopic dermatitis has not been established. Use in children under 12 years of age is not recommended.
253

254 **12.3 Pharmacokinetics**

255 Topical corticosteroids can be absorbed from intact healthy skin. The extent of
256 percutaneous absorption of topical corticosteroids is determined by many factors,
257 including the product formulation and the integrity of the epidermal barrier. Occlusion,
258 inflammation, and/or other disease processes in the skin may also increase
259 percutaneous absorption. Once absorbed through the skin, topical corticosteroids are
260 metabolized, primarily in the liver, and are then excreted by the kidneys. Some
261 corticosteroids and their metabolites are also excreted in the bile.
262

263 **13 NONCLINICAL TOXICOLOGY**

264 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

265 Long-term animal studies have not been performed to evaluate the carcinogenic
266 potential of OLUX Foam or clobetasol propionate.
267

268 In a 90-day repeat-dose toxicity study in rats, topical administration of clobetasol
269 propionate foam at dose concentrations from 0.001% to 0.1% or from 0.03 to 0.3
270 mg/kg/day of clobetasol propionate resulted in a toxicity profile consistent with long-term
271 exposure to corticosteroids including adrenal atrophy, histopathological changes in
272 several organs systems indicative of severe immune suppression, and opportunistic
273 fungal and bacterial infections. A no observable adverse effect level (NOAEL) could not
274 be determined in this study. Although the clinical relevance of the findings in animals to
275 humans is not clear, sustained glucocorticoid-related immune suppression may increase
276 the risk of infection and possibly the risk for carcinogenesis.
277

278 Topical doses of 0% (foam vehicle), 0.001%, 0.01%, and 0.05% clobetasol propionate
279 foam were evaluated in a 52-week dermal photocarcinogenicity study (40 weeks of
280 treatment followed by 12 weeks of observation) conducted in hairless albino mice with
281 concurrent exposure to low-level ultraviolet radiation. Topical treatment with increasing
282 concentrations of clobetasol propionate foam did not have an adverse effect in this
283 study.
284

285 The results of this study suggest that topical treatment with OLUX Foam would not
286 enhance photocarcinogenesis.
287
288
289

290 Clobetasol propionate was nonmutagenic in 4 different test systems: the Ames test, the
291 mouse lymphoma test, the *Saccharomyces cerevisiae* gene conversion assay, and the
292 *E. coli* B WP2 fluctuation test. In the in vivo mouse micronucleus test, a positive finding
293 was observed at 24 hours, but not at 48 hours, following oral administration at a dose of
294 2,000 mg/kg.

295
296 Studies in the rat following subcutaneous administration of clobetasol propionate at
297 dosage levels up to 0.05 mg/kg per day revealed that the females exhibited an increase
298 in the number of resorbed embryos and a decrease in the number of living fetuses at
299 the highest dose.

300
301

302 **14 CLINICAL STUDIES**

303

304 **14.1 Scalp Psoriasis**

305 A well-controlled clinical trial evaluated 188 subjects with moderate to severe scalp
306 psoriasis. Subjects were treated twice daily for 2 weeks with one of 4 treatments: OLUX
307 Foam, vehicle foam, a commercially available clobetasol propionate solution
308 (TEMOVATE[®] Scalp Application), or vehicle solution. The efficacy of OLUX Foam in
309 treating scalp psoriasis at the end of the 2 weeks' treatment was superior to that of
310 vehicle (foam and solution), and was comparable to that of TEMOVATE Scalp
311 Application (Table 2).

312

313 **Table 2. Efficacy Results From a Controlled Clinical Trial in Scalp Psoriasis**

	OLUX Foam n (%)	Vehicle Foam n (%)
Total number of subjects	62	31
Subjects with treatment success ^a	39 (63)	1 (3)
Subjects with parameter Clear at endpoint (scalp psoriasis)		
Scaling - Clear at endpoint	42 (68)	3 (10)
Erythema - Clear at endpoint	27 (44)	2 (6)
Plaque Thickness - Clear at endpoint	41 (66)	3 (10)

314 ^a Defined as a composite of an Investigator's Global Assessment of "completely clear " or "almost clear," a plaque
315 thickness score of 0, an erythema score of 0 or 1, and a scaling score of 0 or 1 at endpoint, scored on a severity
316 scale of 0 to 4.

317

318 **14.2 Non-scalp Psoriasis**

319 Another well-controlled clinical trial evaluated 279 subjects with mild to moderate
320 plaque-type psoriasis (mean body surface area at baseline was 6.7% with a range from
321 1% to 20%) of non-scalp regions. Subjects were treated twice daily for 2 weeks with
322 OLUX Foam or vehicle foam. The face and intertriginous areas were excluded from
323 treatment. The efficacy of OLUX Foam in treating non-scalp psoriasis at the end of 2
324 weeks' treatment was superior to that of vehicle foam (Table 3).

325
326

Table 3. Efficacy Results From a Controlled Clinical Trial in Non-scalp Psoriasis

	OLUX Foam n (%)	Vehicle Foam n (%)
Total number of subjects	139	140
Subjects with treatment success ^a	39 (28)	4 (3)
Physician's Static Global Assessment -Clear or almost clear at endpoint	94 (68)	30 (21)
Scaling - Clear or almost clear at endpoint	101 (73)	42 (30)
Erythema - Clear or almost clear at endpoint	88 (63)	35 (25)
Plaque Thickness - Clear at endpoint	44 (32)	5 (4)

327 ^a Defined as a composite of a Physician's Static Global Assessment score of 0 or 1, scaling score of 0 or 1, an
328 erythema score of 0 or 1 and a plaque thickness score of 0, based on a severity scale of 0 to 5 at endpoint.
329
330

331 16 HOW SUPPLIED/STORAGE AND HANDLING

332 333 16.1 How Supplied

334 OLUX Foam is a white aerosol foam, supplied as follows:

- 335 • 50-g aluminum can NDC 40076-031-50
- 336 • 100-g aluminum can NDC 40076-031-00

337 338 16.2 Storage and Handling

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

340
341 FLAMMABLE. AVOID FIRE, FLAME, OR SMOKING DURING AND IMMEDIATELY
342 FOLLOWING APPLICATION. Contents under pressure. Do not puncture or incinerate.

343 Do not expose to heat or store at temperatures above 120°F (49°C).

344 Keep out of reach of children.
345
346

347 17 PATIENT COUNSELING INFORMATION

348 See FDA-approved patient labeling (Patient Information and Instructions for Use)

349 Inform patients of the following:

- 351 • Avoid use of OLUX Foam on the face, underarms, or groin areas unless directed by
352 the physician.
- 353 • Do not occlude the treatment area with bandage or other covering, unless directed
354 by the physician.
- 355 • Note that local reactions and skin atrophy are more likely to occur with occlusive
356 use, prolonged use or use of higher potency corticosteroids.
- 357 • Discontinue therapy when control is achieved. If no improvement is seen within 2
358 weeks, contact the physician.
- 359 • For proper dispensing of foam, hold the can upside down and depress the actuator.
360 Dispensing directly onto hands is not recommended (unless the hands are the
361 affected area), as the foam will begin to melt immediately upon contact with warm
362 skin.

- 363 • Limit treatment to 2 consecutive weeks. Use no more than 50 grams of OLUX Foam
364 per week, or more than 21 capfuls per week.
- 365 • Report any signs of local adverse reactions to the physician. Advise patients that
366 local reactions and skin atrophy are more likely to occur with occlusive use or
367 prolonged use.
- 368 • Avoid use of OLUX Foam in the diaper area, as diapers or plastic pants may
369 constitute occlusive dressing.
- 370 • The product is flammable; avoid heat, flame, and smoking when applying this
371 product.
- 372 • Do not use other corticosteroid-containing products without first consulting with the
373 physician.

374
375 OLUX is a registered trademark of Stiefel Laboratories, Inc.

376
377 For additional information:
378 1-866-897-5002
379 or visit
380 www.olux.com

381
382 Manufactured for
383 
384 Prestium Pharma, Inc.
385 Newtown, PA 18940
386 By DPT Laboratories, Ltd.
387 San Antonio, TX 78215
388 ©2013 Delcor Asset Corporation, an affiliate of Prestium Pharma, Inc.

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390 OLX:XPI

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PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

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Patient Information
OLUX[®] (O-lux)
(clobetasol propionate) Foam

422 **Important:** OLUX Foam is for use on the skin only. Do not get OLUX Foam near or in your
423 eyes, mouth, or vagina.

424 **What is OLUX Foam?**

425 OLUX Foam is a prescription corticosteroid medicine used on the skin (topical) or scalp to
426 treat adults and children 12 years and older with certain skin conditions that cause red,
427 flaky, and itchy skin.

428 It is not known if OLUX Foam is safe and effective in children under 12 years of age.

429 **Before using OLUX Foam, tell your healthcare provider about all of your**
430 **conditions, including if you:**

- 431 • have had irritation or other skin reaction to a steroid medicine in the past.
- 432 • have a skin infection. You may need medicine to treat the skin infection before using
433 OLUX Foam.
- 434 • have diabetes.
- 435 • have adrenal gland problems.
- 436 • have liver problems.
- 437 • plan to have surgery.
- 438 • are pregnant or plan to become pregnant. It is not known if OLUX Foam will harm your
439 unborn baby. Talk to your healthcare provider if you are pregnant or plan to become
440 pregnant.
- 441 • are breastfeeding or plan to breastfeed. It is not known if OLUX Foam passes into your
442 breast milk. Do not apply OLUX Foam to your chest area if you are breastfeeding a baby.
443 This will help to prevent the baby from accidentally getting OLUX Foam into the baby's
444 mouth.

445 Tell your healthcare provider about all the medicine you take including prescription or over-
446 the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare
447 provider if you take other corticosteroid medicines by mouth, or injection, or use other
448 products on your skin or scalp that contain corticosteroids.

449 **How should I use OLUX Foam?**

- 450 • Use OLUX Foam exactly as your healthcare provider tells you to use it.
- 451 • This medicine is for use on the skin or scalp only. Do not get OLUX Foam in your eyes,
452 mouth, or vagina.
- 453 • Apply OLUX Foam 2 times each day, 1 time in the morning and 1 time in the evening, or
454 as directed by your healthcare provider.
- 455 • OLUX Foam should not be used if you have skin thinning (atrophy) at the treatment
456 area.
- 457 • Avoid using OLUX Foam on your face, underarms, or groin area.
- 458 • Do not bandage or cover your treated area unless your healthcare provider tells you to.
- 459 • Do not use OLUX Foam for longer than 2 weeks in a row.
- 460 • You should not use more than 50 grams or 21 capfuls of OLUX Foam in 1 week.

- 461 • Talk to your healthcare provider if your skin or scalp does not improve after 2 weeks of
462 treatment with OLUX Foam.
463 • See your healthcare provider regularly to check your symptoms and side effects while
464 using OLUX Foam.
465 **See the “Instructions for Use” at the end of the Patient Information for detailed**
466 **information about the right way to apply OLUX Foam.**

467 **What should I avoid while using OLUX Foam?**

468 **OLUX Foam is flammable.** Avoid heat, flames, or smoking during and right after you
469 apply it to your skin.

470 **What are the possible side effects of OLUX Foam?**

471 **OLUX Foam may cause serious side effects, including:**

- 472 • **Symptoms of a disorder where the adrenal gland does not make enough of**
473 **certain hormones (adrenal insufficiency) during treatment or after stopping**
474 **treatment.** Your healthcare provider may do blood tests to check for adrenal
475 insufficiency while you are using OLUX Foam. Tell your healthcare provider if you have
476 any of these persistent symptoms of adrenal insufficiency:
477 o tiredness that worsens and does not go away, muscle weakness
478 o loss of appetite
479 o nausea or vomiting
480 o dizziness or fainting
481 o irritability and depression
482 o weight loss
483 • **Cushing’s syndrome, when the body is exposed to too much of the hormone**
484 **cortisol.** Your healthcare provider may do tests to check for this. Symptoms can
485 include:
486 o weight gain, especially around your upper back and midsection
487 o tiredness and muscle weakness
488 o roundness of your face (moon face)
489 o slow healing of cuts, insect bites, and infections
490 o depression, anxiety, and irritability
491 o new or worsening high blood pressure
492 • **High blood sugar (hyperglycemia) or diabetes mellitus that has not been**
493 **diagnosed can happen with treatment.** Your healthcare provider may do tests to
494 check you for this.
495 • **Skin problems, including reactions where OLUX Foam is applied, skin**
496 **infections, and allergic reactions** (allergic contact dermatitis). Tell your healthcare
497 provider if you get any new skin problems.
498 • **Effects on growth and weight in children.**

499
500 **The most common side effects of OLUX Foam** include burning and skin reactions at the
501 treated site.

502
503 These are not all the possible side effects of OLUX Foam.

504 Call your doctor for medical advice about side effects. You may report side effects to FDA at
505 1-800-FDA-1088.

506 **How should I store OLUX Foam?**

- 507 • Store the OLUX Foam at room temperature, between 68°F to 77°F (20°C to 25°C).
508 • Contents are flammable. Keep the can away from fire and heat.

- 509 • Do not pierce or burn the can of OLUX Foam. Never throw the can into a fire, even if the
510 can is empty.

511 **Keep OLUX Foam and all medicines out of the reach of children.**

512 **General information about the safe and effective use of OLUX Foam.**

513 Medicines are sometimes prescribed for purposes other than those listed in a Patient
514 Information leaflet. You can ask your healthcare provider or pharmacist for information
515 about OLUX Foam that is written for health professionals. Do not use OLUX Foam for a
516 condition for which it was not prescribed. Do not give OLUX Foam to other people, even if
517 they have the same condition that you have. It may harm them.

518 **What are the ingredients in OLUX Foam?**

519 **Active ingredient:** clobetasol propionate, USP, 0.05%

520 **Inactive ingredients:** cetyl alcohol, citric acid, ethanol (60%), polysorbate 60, potassium
521 citrate, propylene glycol, purified water, and stearyl alcohol pressurized with a hydrocarbon
522 (propane/butane) propellant

523 Manufactured for:

524 Prestium Pharma, Inc., Newtown, PA 18940 By DPT Laboratories, Ltd., San Antonio, TX 78215

525 For more information, go to www.olux.com or call 1-866-897-5002.

526 ©2013 Delcor Asset Corporation, an affiliate of Prestium Pharma, Inc.

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

Revised: April 2014

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532

Instructions for Use OLUX[®] (O-lux) (clobetasol propionate) Foam

533 **Important:** OLUX Foam is for use on the skin only. Do not get OLUX Foam near
534 or in your eyes, mouth or vagina.

535 **How should I apply OLUX Foam?**

- 536 • Apply OLUX Foam, 2 times a day, 1 time in the morning and 1 time in the
537 evening, or as directed by your healthcare provider.
- 538 • Apply only enough to cover the affected areas. OLUX Foam should not be
539 applied to the groin, armpits, or other skin fold areas.

540 To use OLUX Foam:



Figure A

Step 1: Before applying OLUX 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 B

Step 2: Turn the can upside down.

Push the button to squirt a small amount of OLUX Foam into the cap of the can, onto a saucer or other cool surface, or on your affected skin area. (see **Figure B**) This amount should be no more than 1½ capfuls, about the size of a golf ball.

Do not squirt OLUX Foam directly onto your hands (unless your hands are the affected areas), because the foam will begin to melt right away on contact with your warm skin.

If your fingers are warm, rinse them in cold water first. Be sure to dry them thoroughly before handling the foam.

If the can seems warm or the foam seems runny, run the can under cold water.

Step 3: Using your fingertips, gently massage OLUX Foam into the affected areas until the foam disappears. (see **Figures C and D**)



Figure C



Figure D



Figure E

Step 4: If you are treating areas with hair, such as the scalp, move any hair away so that the foam can be applied directly to the affected areas. (see **Figure E**)

Repeat the process until the affected areas are treated.

Keep the foam away from your eyes, as it will sting and may cause eye problems if there is frequent contact with your eyes. If the foam gets in your eyes, rinse them well with cold water right away. If the stinging continues, contact your healthcare provider right away.



Step 5: Wash your hands after applying OLUX Foam. (see **Figure F**)

Throw away any of the unused medicine that you squirted out of the can.

Figure F

541 **How should I store OLUX Foam?**

- 542
- Store the OLUX Foam at room temperature, between 68°F to 77°F (20°C to 25°C).
 - Contents are flammable. Keep the can away from fire and heat.
- 543
- Do not pierce or burn the can of OLUX Foam. Never throw the can into a fire, even if the
- 544
- can is empty.
- 545

546 **Keep OLUX Foam and all medicines out of the reach of children.**

547 This Instructions for Use has been approved by the U.S. Food and Drug
548 Administration.

549 Manufactured for: Prestium Pharma, Inc. Newtown, PA 18940

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