

PRODUCTS

Nail Lacquer for Onychomycosis

Ciclopirox Topical Solution, 8% (Nail Lacquer), has been approved by the Food and Drug Administration for the topical treatment of onychomycosis of the fingernails and toenails. For more information, contact Taro Pharmaceutical Industries Ltd. by visiting www.taro.com.

Laser Comb Gets FDA Clearance

The Food and Drug Administration has given clearance to the HairMax LaserComb, which is indicated to promote hair growth in people who are bald or have

thinning hair. The comb costs \$545.00 and is available online at www.hairmax.com.

Fractional Laser

The MiXto SX CO₂ laser is available for skin resurfacing and rejuvenation. The laser delivers tight, 0.3-mm spots. An algorithm divides the treatment area into four quadrants and skips the beam from quadrant to quadrant so that each strike is separated by the longest possible interval. The process is repeated until the entire area is treated. Dividing the laser energy in this way allows most procedures to be

done quickly and without anesthesia. For more information, contact Lasering USA by visiting www.laseringusa.com.

Mineral Moisturizer

EmerginC Earth is a midweight cream containing Phytelene-based copper, iron, manganese, and magnesium, as well as collagen and elastin. The cream hydrates the skin and improves tone and texture. For more information, contact emerginC by calling 800-257-9597.

Fluorescent Acne Treatment

The Tru-Blu lamp has been approved by the Food and Drug Administration for

treatment of acne. The lamp's 417-nm blue fluorescent light kills *Propionibacterium acnes* bacteria. Treatment sessions last 15 minutes and are painless. Patients sit with the affected area close to the light source for 1-2 sessions per week for 5-6 weeks. For more information, contact National Biological Corp. at 800-338-5045.

Emu Oil Serum for Scarred Skin

Transdermis Scar Therapy, a serum made from emu oil, claims to reduce the swelling, redness, and irritation associated with scars. The serum is hypoallergenic and also contains the essential fatty acids omega-3, omega-6 and omega-9, which have demonstrated healing effects on the skin. For more information, contact Transdermis by visiting www.transdermis.com.

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Locoid Lipocream®

(hydrocortisone butyrate 0.1%) Cream

Combines efficacy with elegance

Lipid-Rich Relief for Atopic Dermatitis

- Prescribe the #1 brand of midpotency corticosteroid cream*
- Features Hydrolipid Technology™ to hydrate and help to repair the skin barrier through a unique blend of lipids and water¹
- Now available exclusively from Triax® Pharmaceuticals. Call 1-866-733-3639 for samples

Efficacy & Elegance

Locoid Lipocream® (hydrocortisone butyrate 0.1%) Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. Prolonged use may produce reversible HPA suppression. May cause local adverse reactions, including itching, irritation, and dryness.

*IMS NPA July 2007.
Reference: 1. Fowler JF Jr, Fransway AF, Jackson JM, Rohowsky N. Hydrocortisone butyrate 0.1% cream in the treatment of chronic dermatitis. *Cutis*. 2005;75(2):125-131.

For Dermatological Use Only
BRIEF SUMMARY—Please see full Prescribing Information for complete product information
CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. **PRECAUTIONS General:** Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which increase the risk of systemic toxicity include the application of more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See PRECAUTIONS - PEDIATRIC USE.) If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled. **Information for the Patient:** 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. 2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed. 3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive. 4. Patients should report any signs of local adverse reactions. 5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings. **Laboratory Tests:** The following tests may be helpful in evaluating the HPA axis suppression: Urinary free cortisol test, ACTH stimulation test. **Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity in *Salmonella* raphimurium strains TA98, TA100, and TA92 with prednisolone and hydrocortisone have revealed negative results. **Pregnancy: Teratogenic Effects: Pregnancy Category C:** Corticosteroids are generally 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. In teratogenicity studies, topical administration of 1% or 10% hydrocortisone butyrate in an ointment to pregnant Wistar rats (gestational days 6-15) or New Zealand white rabbits (gestational days 6-18) resulted in no teratogenic findings. However, a dose-dependent increase in fetal resorptions was reported in rabbits, and fetal resorptions were observed in rats treated with 10% hydrocortisone butyrate. The doses given to rats are approximately 8 to 80 times the human topical dose based on a body surface area comparison (assuming 100% absorption). For rabbits, the doses given were approximately 0.2 and 2 times the human topical dose. Increased resorptions were also noted in Wistar rats given subcutaneous administrations of hydrocortisone butyrate (9 mg/kg/day; 3 times the human topical dose) on gestational days 9 through 15. In CS mice given subcutaneous administrations of 1 mg/kg/day (0.2 times the human topical dose), an increased number of cervical ribs and one fetus with clubbed legs was reported. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Locoid Lipocream® (hydrocortisone butyrate 0.1%) Cream should not be used extensively on pregnant patients, in large amounts, or for longer than two weeks. **Nursing Mothers:** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities *not* likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. *Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.* HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Chronic corticosteroid therapy may interfere with the growth and development of children. **ADVERSE REACTIONS:** The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. **OVERDOSAGE:** Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS.)

Rx only
Locoid Lipocream is a registered trademark of Astellas Pharma Europe B.V. licensed to Triax Pharmaceuticals, LLC.



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