



F O R I M M E D I A T E R E L E A S E

New Pediatric Indication for Locoid Lipocream[®] (hydrocortisone butyrate, 0.1%) Cream, the Leading Mid-Potency Brand of Topical Corticosteroids

New Studies Confirm Safety and Efficacy for Children with Atopic Dermatitis As Young as 3 Months of Age

Cranford, NJ- October 21, 2009 - Triax Pharmaceuticals, LLC announced today the approval of new labeling for Locoid Lipocream (hydrocortisone butyrate, 0.1%), the leading mid-potency corticosteroid brand indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adults. *The new labeling now includes an indication for topical treatment of mild to moderate atopic dermatitis in pediatric patients 3 months of age to 18 years of age.*

Atopic dermatitis is the most common skin disorder seen in infants and children. It affects nearly 15 million people in the United States (15% to 20% of children and 1% to 3% of adults),¹ and accounts for 10 to 20 percent of all visits to dermatologists. The key symptom is pruritus (itching), leading to the description of eczema as "the itch that rashes." Topical corticosteroids have become the cornerstone of treatment for a variety of inflammatory dermatoses, including atopic dermatitis (AD), eczema, and psoriasis.¹

Locoid Lipocream is the mid-potency corticosteroid cream with the highest concentration of barrier-enhancing lipids providing the hydrating power of an ointment with the elegance of a cream. The unique combination of 70% lipids dispersed in 30% water provides excellent ability to minimize transepidermal water loss and help restore the skin barrier.² Locoid Lipocream now meets the needs of younger patients and infants 3 months of age with mild to moderate atopic dermatitis with the following benefits:

- Forms occlusive barrier that soothes skin and promotes healing³
- Propylene glycol-free for patients who can't tolerate stinging
- Non-halogenated which allows for low risk of potential side effects.
- Contains no known irritants (e.g. imidurea, lanolin)
- Fragrance-free base.

A large pivotal study confirmed treatment success with Locoid Lipocream on 3 levels:

1. More than 60% of patients were determined "clear" or "almost clear" as measured by Physician's Global Assessment (PGA) (n=264);⁴
2. Body Surface Area (BSA) Evaluation showed significant effects favoring Locoid Lipocream.
3. Locoid Lipocream was also measured as "superior" by pruritus scores⁴
 - 43% of patients treated with Locoid Lipocream had at least a 2-point improvement in itching, compared to 21% of vehicle-treated patients.⁴
 - 80% of Locoid Lipocream-treated patients had at least a 1-point improvement vs 54% for vehicle.⁴

Additional benefits of Locoid Lipocream include very low HPA axis suppression in patients 3 months of age and older (n= 84)⁵, only 5 of 84 patients (6%) showed laboratory evidence of HPA axis suppression. Adverse events in the large clinical pediatric study (n = 264) in atopic dermatitis were limited to application site reactions and acne but were not statistically different than the vehicle.⁵ Pediatric patients in all studies were treated for up to 4 weeks with Locoid Lipocream.⁵

In addition to industry leader Locoid Lipocream, Triax Pharmaceuticals also markets Locoid Lotion (hydrocortisone butyrate, 0.1%), the only class 5 corticosteroid lotion indicated for patients with AD ages 3 months of age and older. Locoid Lotion has a moisturizing vehicle with a high concentration of barrier-enhancing lipids to cover larger areas and hairy areas of affected skin.

Locoid Lipocream is available in a 15g, 45g or a 60g tube.
Locoid Lotion is available in a 2 fl. oz. or a 4 fl. oz. bottle.

Important Safety Information

Locoid Lipocream and Locoid Lotion are not for oral, ophthalmic or intravaginal use.

Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Before prescribing for more than 2 weeks, any additional benefits of extending treatment to 4 weeks should be weighed against the risk of HPA axis suppression and local adverse events. The safety and efficacy of Locoid Lipocream has not been established beyond 4 weeks of use. Reversible HPA axis suppression may occur with the potential for corticosteroid insufficiency. Consider periodic evaluations for HPA axis suppression if applied to large surface areas or used under occlusion. Systemic effects of topical corticosteroids may also include manifestations of Cushing's syndrome, hyperglycemia, and glucosuria. Pediatric patients may be more susceptible to systemic toxicity due to their large skin surface-to-body-mass ratios. Initiate appropriate therapy if a concomitant skin infection develops. Discontinue use if irritation develops.

About Triax Pharmaceuticals, LLC

Triax Pharmaceuticals is a specialty pharmaceutical company with integrated sales, marketing, and development expertise that markets a portfolio of branded dermatological products including Locoid Lipocream, Locoid Lotion, Tretin-X[®] Kits, and Minocin[®] Kits. Triax focuses on marketing dermatology products in the United States.

For more information on Locoid Lipocream or other Triax products, please contact
Peter Volk or Aleen Hosdaghian of Triax Pharmaceuticals, LLC, 908.372.0500.
See www.locoid.com for full prescribing information.

*84 patients were maximally challenged to determine HPA axis suppression. Disease severity (moderate to severe AD affecting at least 25% of BSA) and dosing frequency (3 times/daily for up to 4 weeks) differed from those for which Locoid Lipocream is indicated (mild-to-moderate AD dosed 2 times/daily for up to 4 weeks). HPA axis suppression was defined by a serum cortisol level of <18mcg/dL following cosyntropin stimulation.

1. http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/default.asp#link_b
2. Halkier-Sorensen L. Occupational skin diseases. Contact Dermatitis. 1996;35(1 Suppl):1-120.
3. Fowler JF Jr. Hydrocortisone butyrate 0.1% cream in the treatment of chronic dermatitis. *Cutis* 2005;75:125-131.
4. Abramovits W, Alvarez Connelly E, Breneman D, et al. A vehicle-controlled study of hydrocortisone butyrate 0.1% lipocream cream in children with atopic dermatitis. *Cutis*. 2009;
5. Matheson R, Kempers S, Breneman D, et al. Hydrocortisone butyrate 0.1% lotion in the treatment of atopic dermatitis in pediatric subjects. *J Drugs Dermatol*. 2008;7:266-271.