



PDL DRUG REVIEW

Proprietary Name: Eucrisa®

Common Name: crisaborole

PDL Category: Atopic Dermatitis

<u>Comparable Products</u>	<u>Preferred Drug List Status</u>
Elidel	Non-Preferred with Conditions
Protopic	Non-Preferred with Conditions

Summary

Pharmacology/Usage: Crisaborole, the active ingredient of Eucrisa®, is a phosphodiesterase-4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. The exact mechanism for which crisaborole works for its approved indication is not well defined.

Indications: For topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older.

There is no pregnancy category with this medication; however, the risk summary indicates there is no available data with use in pregnant women to inform the drug-associated risk for major birth defects and miscarriage. The safety and efficacy of use in the pediatric population below 2 years of age have not been established.

Dosage Forms: Topical ointment: 2% (20mg/gm)

Recommended Dosage: Apply a thin layer twice daily to the affected area.

Drug Interactions: There were no drug interactions listed with this product.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Eucrisa®) minus reported % incidence for placebo. Please note that an incidence of 0% means the incidence was the same as or that the active drug was less than its comparator.* The most frequently reported adverse event included application site pain (3%). Application site pain refers to skin sensations such as burning or stinging.

Hypersensitivity reactions, including contact urticaria, have been reported in subjects treated with Eucrisa®. If signs and symptoms of hypersensitivity occur, it is recommended to discontinue Eucrisa® immediately and start appropriate treatment.

Contraindications: In patients with known hypersensitivity to crisaborole or any component of the formulation

Manufacturer: Anacor Pharmaceuticals, Inc

Analysis: There were 2 multicenter, randomized, double-blind, parallel-group vehicle-controlled studies performed to assess the safety and efficacy of crisaborole when used in subjects (N=1522 total) with atopic dermatitis. Included in the studies were subjects aged 2 to 79 years of age with a 5% to 95% treatable body surface area. At

baseline, 38.5% of the subjects had an Investigators Static Global Assessment (ISGA) score of 2 (mild) and 61.5% had an ISGA score of 3 (moderate) in the overall assessment of atopic dermatitis on a severity scale of 0 to 4.

In both studies, subjects were randomized to crisaborole ointment or vehicle ointment BID for 28 days, and the primary endpoint assessed was the proportion of subjects at day 29 who achieved success. Success was defined as an ISGA grade of Clear (score of 0) or Almost Clear (score of 1), with a 2-grade or greater improvement from baseline. Results can be found in the table below, which was adapted from the prescribing information.

	Trial 1		Trial 2	
	Eucrisa® (N=503)	Vehicle (N=256)	Eucrisa® (N=513)	Vehicle (N=250)
Success in ISGA	32.8%	25.4%	31.4%	18%
Calculated NNT (by CHC)	14		8	

Place in Therapy: Eucrisa®, a new topical PDE-4 inhibitor, is indicated for the treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. It was found to be effective as compared with placebo; however, comparator trials with other active agents have not been found. This ointment offers prescribers an alternative treatment option, possibly without the safety concerns seen, for example, with Elidel® or Protopic®; however, currently available data regarding safety is based on very limited durations of therapy.

There is no evidence to support that Eucrisa® is more effective than the currently available, more cost effective. It is therefore recommended that Eucrisa® remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

PDL Placement: Preferred
 Non-Preferred with Conditions

References

¹ Eucrisa [package insert]. Palo Alto, CA: Anacor Pharmaceuticals, Inc; 2016.