RXADVANCE
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Eucrisa (crisaborole) Topical Ointment
Clinical Update

Clinical Update: FDA Approves Eucrisa (crisaborole) Ointment 2% in Children as Young as 3 Months of Age With Mild-to-Moderate Atopic Dermatitis.
FDA approval date: March 23, 2020

Crisaborole ointment, 2%, is a novel, steroid-free, topical phosphodiesterase (PDE4) inhibitor. It is approved in the U.S. as Eucrisa® (crisaborole ointment, 2%) for topical treatment of mild-to-moderate AD in adults and pediatric patients 3 months of age and older. Crisaborole is also approved in Canada as EUCRISA® (crisaborole ointment, 2%) and Israel and Australia as STAQUIS™ (crisaborole ointment, 2%) for mild-to-moderate atopic dermatitis (AD) in patients 2 years of age and older.

EUCRISA is a prescription ointment used on the skin (topical) to treat mild-to-moderate eczema (atopic dermatitis) in adults and pediatric patients 3 months of age and older.

The sNDA submission was based on data from the Phase 4 CrisADe CARE 1 trial. The four-week, multicenter, open-label, single-arm study evaluated the safety of crisaborole ointment, 2%, applied twice daily in 137 pediatric patients who were 3 months to less than 24 months of age, with effectiveness as an exploratory endpoint. All patients had mild-to-moderate AD involving at least 5% treatable body surface area (%BSA), excluding the scalp. A cohort of 21 of the 137 subjects was included in a subgroup for pharmacokinetic (PK) assessment, with clinical diagnoses of moderate AD and a minimum of 35% treatable %BSA, excluding the scalp.