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Crisaborole

Approved indication: atopic dermatitis

Staquis (Pfizer)
tubes containing 2.5 mg and 60 mg 2% ointment

When mild to moderate atopic dermatitis does not respond to moisturisers and emollients, low-dose corticosteroids are usually prescribed. Crisaborole 2% ointment is a new treatment for this condition and is approved for patients aged two years and over. It is a phosphodiesterase type 4 inhibitor and, although its mechanism of action is not clear, inhibiting the phosphodiesterase type 4 enzyme is known to suppress the secretion of pro-inflammatory cytokines such as tumour necrosis factor (TNF) alpha.

A thin layer of ointment should be applied to affected skin twice a day. After administration, 25% of the dose is absorbed. Crisaborole is then rapidly metabolised to inactive metabolites which are excreted by the kidneys. Drug interactions with cytochrome P450 enzymes are not expected. Concurrent use with other topical treatments for atopic dermatitis has not been evaluated.

Crisaborole has been investigated in two identical placebo-controlled studies of 1522 participants.[1] Most of them were children. They were evaluated using the Investigator's Static Global Assessment score (severity scale of 1–4). At baseline, 38.5% of patients had mild disease (score of 2) and 61.5% had moderate disease (score of 3). Crisaborole ointment or vehicle alone was applied twice a day for 28 days. The primary end point of the trials was the proportion of patients who had clear (score of 0) or almost clear (score of 1) skin and at least a 2-point improvement in their score from baseline. At the end of the study period, significantly more of the patients who applied active treatment compared to placebo had successfully responded (31–33% vs 18–25% of patients) (see Table).

Crisaborole ointment was well tolerated in the trials. The most common treatment-related adverse effect was burning or stinging at the application site. This affected 4.4% of those in the crisaborole group and 1.2% in the control group.[1] Contact urticaria has been reported with this ointment (<1% of patients). A 48-week, single-arm extension trial of 517 participants assessed the long-term safety of 28-day treatment courses. The most common treatment-related adverse events included worsening or flare of atopic dermatitis (3.1%), and pain (2.3%) and infection (1.2%) at the application site.[2]

Topical crisaborole seemed to be effective as a short-term treatment for mild to moderate atopic dermatitis. However, there have been no comparative trials with topical corticosteroids so far. Longer-term efficacy is yet to be established.

T T manufacturer provided additional useful information

REFERENCES

1. Paller AS, Wynnis LT, Lebwohl MG, Blumenthal RL, Boguniewicz M, Call RS, et al. Efficacy and safety of crisaborole ointment, a novel nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults. J Am Acad Dermatol 2016;75:494-503. https://doi.org/10.1016/j.jaad.2016.05.046
2. Eichenfield LF, Call RS, Forsha DW, Fowler J Jr, Herbert AA, Spellman M, et al. Long-term safety of crisaborole ointment 2% in children and adults with mild to moderate atopic dermatitis. J Am Acad Dermatol 2017;77:641-9. https://doi.org/10.1016/j.jaad.2017.06.010

The Transparency Score is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 2014;37:27.

At the time the comment was prepared, information about this drug was available on the websites of the Food and Drug Administration in the USA and the Therapeutic Goods Administration.

Table **Efficacy of twice-daily crisaborole 2% ointment for mild–moderate atopic dermatitis**

	Proportion of patients who successfully responded after 28 days of treatment*		
	Crisaborole (1016 patients)	Placebo vehicle (506 patients)	P value
Trial 1	32.8%	25.4%	0.038
Trial 2	31.4%	18%	<0.001

* The primary efficacy end point was the proportion of patients who had clear (score of 0) or almost clear (score of 1) skin evaluated using the Investigator's Static Global Assessment score (severity scale of 1–4), and at least a 2-point improvement in their score from baseline.

Source: reference 1