



CORRECTION

Correction to: Crisaborole Ointment, 2%, for Treatment of Patients with Mild-to-Moderate Atopic Dermatitis: Systematic Literature Review and Network Meta-Analysis

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The authors would like to replace 2 small sections of the published manuscript that refer to a

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qualitative review of safety data for included studies (together with an associated safety table), to provide some further clarifications on these safety data and to include some quantitative updates for rates.

Specifically, the authors would like to replace the paragraph under the “Overall Adverse Events” section of the paper with text provided below, which includes edits to be consistent with updated rates in Kempers paper [28] that are provided in the updated Table 1 below.

Overall Adverse Events

The rates of overall AEs ranged from 15.4% [26] to 86.0% [28]. The rates of patients reporting at least one treatment-emergent AE with crisaborole (29.3% and 29.4%) were similar to the rates experienced in the vehicle group (19.8% and 32.0%) [14]. Rates of overall AEs reported for tacrolimus, 0.03%, ranged from 15.4% [26] to 84.0% [28] across three RCTs, and for tacrolimus, 0.1%, was 32.7% in one RCT [27]. These rates were 16.6% [26] to 86.0% [28] for pimecrolimus across three RCTs.

Additionally, the authors would like to replace the paragraph under the “Common Adverse Events” section of the paper with the text below in order to include clarifications regarding the updated MedDRA term for application site pain that was used in the crisaborole studies, however, this was not used in the studies for comparator agents.

Table 1 Qualitative summary of safety data of included trials

Author, year (trial name)	Intervention/comparator	Adverse events ^a , n/N (%)				
		Overall	Application site	URTI	Skin infection	Erythema
Paller 2016 (AD-301) [14]	Crisaborole, 2%	TEAE: 147/502 (29.3)	Reaction: 48/502 (9.6) Pain: 31/502 (6.2)	14/502 (2.8)	Staphylococcal: 0/502 (0)	Application site: 2/502 (0.4)
	Vehicle	TEAE: 50/252 (19.8)	Reaction: 12/252 (4.8) Pain: 3/252 (1.2)	10/252 (4.0)	Staphylococcal: 1/252 (0.4)	Application site: 1/252 (0.4)
Paller 2016 (AD-302) [14]	Crisaborole, 2%	TEAE: 150/510 (29.4)	Reaction: 27/510 (5.3) Pain: 14/510 (2.7)	16/510 (3.1)	Staphylococcal: 1/510 (0.2)	Application site: 2/510 (0.4)
	Vehicle	TEAE: 79/247 (32.0)	Reaction: 13/247 (5.3) Pain: 3/247 (1.2)	5/247 (2.0)	Staphylococcal: 4/247 (1.6)	Application site: 1/247 (0.4)
Abramovits 2008 [27]	Tacrolimus, 0.1%	32/98 (32.7)	Pain: 3/98 (3.1) Burning: 19/98 (19.4)	NR	0/98 (0)	Application site: 1/98 (1.0)
	Pimecrolimus 1%	21/90 (23.3)	Pain: 0/90 (0) Burning: 12/90 (13.3)	NR	1/90 (0.1)	Application site: 2/90 (2.2)
Schachner 2005 [29]	Tacrolimus, 0.03%	NR/158 (36.7)	Burning or stinging: 30/158 (19.0)	NR	NR	Skin erythema: 12/158 (7.6)
	Vehicle	NR/159 (45.3)	Burning or stinging: 27/159 (17.0)	NR	NR	Skin erythema: 30/159 (18.9)
Chapman 2005 [30]	Tacrolimus, 0.03%	NR	NR	NR	NR	NR
	Vehicle	NR	NR	NR	NR	NR
Paller 2005 [26]	Tacrolimus, 0.03%	32/208 (15.4)	Pain: 4/208 (1.9) Burning: 11/208 (5.3)	NR	0/208 (0)	Application site: 2/208 (1.0)
	Pimecrolimus 1%	36/217 (16.6)	Pain: 4/217 (1.8) Burning: 20/217 (9.2)	NR	0/217 (0)	Application site: 4/217 (1.8)

Table 1 continued

Author, year (trial name)	Intervention/comparator	Adverse events ^a , n/N (%)				
		Overall	Application site	URTI	Skin infection	Erythema
Eichenfield 2002 [24]	Pimecrolimus 1%	NR/136 (44.0)	Burning: NR (10.4)	NR/ 136 (14.2)	NR	NR
	Vehicle	NR/267 (42.6)	Burning: NR (12.5)	NR/ 267 (13.2)	NR	NR
Kempers 2004 [28]	Pimecrolimus 1%	NR (86.0) ^b	Warmth/stinging/ burning: 14/71 (20.0)	NR	Staphylococcal: 3/71 (4)	Application site: 0/71 (0)
	Tacrolimus, 0.03%	NR (84.0) ^b	Warmth/stinging/ burning: 12/70 (17.0)	NR	Staphylococcal: 0/70 (0)	Application site: 2/70 (3.0)
Levy 2005 [25]	Tacrolimus, 0.03%	NR/44 (55.6)	NR	NR	NR	NR
	Vehicle	NR/45 (48.8)	NR	NR	NR	NR

AE adverse event, *NR* not reported, *TEAE* treatment-emergent adverse event, *URTI* upper respiratory tract infection

^a Reporting of AEs varied across studies, with some studies reporting only those AEs experienced by $\geq 5\%$ or $\geq 10\%$ of patients in a study arm

^b The data and reporting for this study suggests that different severity criteria were used that allowed for milder AEs to be included, thereby increasing overall AE rates.

Common Adverse Events

Frequently reported AEs were application site burning/stinging, upper respiratory tract infections, skin infections, and erythema (Table 1). The incidence of application site burning/stinging varied across studies and depended on the outcome definition: some studies included pain or warmth, whereas others reported only burning or stinging. For the crisaborole studies, application site pain was coded using the updated MedDRA term, which refers to skin sensation such as burning or stinging. For crisaborole studies, application site pain AEs were 6.2% [AD-301] and 2.7% [AD-302] versus 1.2% for vehicle in each study [14]. Rates for pain at site of application (not including burning or stinging) were 1.9% for tacrolimus 0.03% versus

1.8% for pimecrolimus [26] and 3.1% for tacrolimus 0.1% versus 0% for pimecrolimus [27]. The reported rate for burning or stinging for tacrolimus 0.03% was 19.0% [29] and the rate for burning for tacrolimus 0.1% was 19.4% [27]. Rates for burning for pimecrolimus were reported across three studies as ranging from 9.2% to 13.3% [26, 27]. Additional data for warmth/burning/stinging are presented in Table 1. Only three RCTs reported the rates of upper respiratory tract infections (2.0% [14] to 14.2% [24]). The incidence of skin infections across all RCTs was generally low (Table 1). The incidence of erythema ranged from 0% [14, 28] to 18.9% [29], but with various definitions of erythema (Table 1).

Lastly, the authors would like to replace the associated safety table (Table 1) with an updated version of this table that includes several additional labels for adverse events, edits for some of the reported rates (very small quantitative edits for most changes, except for those for Kempers study [28]), and inclusion of an additional footnote for further clarification.

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