

16007

**Ixekizumab demonstrated longer medication persistence than other biologics in the treatment of psoriasis patients: Results from IBM MarketScan databases**



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**Objective:** To assess the medication persistence in psoriasis patients treated with ixekizumab, secukinumab, adalimumab, ustekinumab, or etanercept.

**Methods:** Study patients were diagnosed with psoriasis from 7/1/2016 to 1/1/2018 from IBM MarketScan Databases with the first claim (defined as the index date) of ixekizumab (n = 722), secukinumab (n = 917), adalimumab (n = 3361), ustekinumab (n = 1804), or etanercept (n = 494) and had 6 months pre- and 1 year post-index continuous eligibility. Patients with other disease conditions (rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, inflammatory bowel disease), within 6 months pre-index, and had label indications for these biologics were excluded. Medication persistence between ixekizumab and other biologics studied was compared using survival analysis on time to the first medication gap of >60 days. Cox proportion hazards model was used to obtain the hazard ratio (HR) on medication persistence after inverse probability of treatment weighting (IPTW) to address cohort imbalances. Sensitivity analysis was conducted using data with prior 12-month eligibility criteria.

**Results:** Ixekizumab showed significantly longer medication persistence versus secukinumab (median: 358 vs 332 days, HR: 0.80,  $P < .001$ ), adalimumab (median: 356 vs 298 days, HR: 0.82,  $P < .001$ ), ustekinumab (median: 357 vs 174 days, HR: 0.54,  $P < .001$ ), and etanercept (median: 357 vs 188 days, HR: 0.48,  $P < .001$ ). Consistent results were observed using data with 1-year pre-index eligibility criteria.

**Conclusions:** The results of this study suggest that psoriasis patients were more persistent to ixekizumab medication than other biologics in the treatment of psoriasis patients in the real world.

*Commercial disclosure: 100% sponsored by Eli Lilly and Company.*

16018

**Safety, efficacy, and pharmacokinetics of crisaborole ointment, 2%, in infants aged 3 to < 24 months with mild to moderate atopic dermatitis**



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**Background:** Crisaborole is a nonsteroidal phosphodiesterase-4 inhibitor for the treatment of mild to moderate AD.

**Design:** Single-arm open-label phase 4 trial (NCT03356977; CARE 1).

**Methods:** Infants (3 to <24 months) with Investigator's Static Global Assessment (ISGA) mild (2) or moderate (3) and treatable percentage body surface area (%BSA)  $\geq 5$  received twice-daily crisaborole for 28 days; a cohort with moderate ISGA and %BSA  $\geq 35$  were included in a PK analysis. End points were safety (primary) and efficacy and PK (exploratory).

**Results:** 137 infants were included (mean, 13.6 months [SD, 6.42]; 64.2% male), 21 in the PK cohort (12.7 months [SD, 6.58]; 61.9% male). Treatment-emergent adverse events (AEs) were reported for 88 (64.2%) patients (35.0% had mild); treatment-related AEs were reported for 22 (16.1%). Rates of treatment-related application site pain (3.6%) and application site discomfort (2.9%) were consistent with studies in patients  $\geq 2$  years. 30.2% of patients achieved ISGA clear (0)/almost clear (1) with  $\geq 2$ -grade improvement at day 29. From baseline to day 29, mean (SD) Eczema Area and Severity Index score decreased from 11.8 (8.41) to 5.0 (5.65), and Patient-Oriented Eczema Measure total score improved from 14.8 (6.12) to 6.1 (5.47). Based on nonlinear regression analysis accounting for dose and age differences, crisaborole exposure was comparable with patients  $\geq 2$  years. Mean (SD) values for crisaborole PK parameters were: C(max), 379.3 (8749.7) ng/mL; AUC(tau), 2591 (66,481) h·ng/mL.

**Conclusions:** Crisaborole was well tolerated and effective in infants (3 to <24 months) with mild to moderate AD, and systemic exposures were similar to patients  $\geq 2$  years.

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16030

**Topical application of vitamin C and E compound mixture prevents combined pollutant-induced skin inflammation, oxidation, and loss of cutaneous barrier proteins**



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The skin is one of the main target organs of the harmful effects of environmental insults. In fact, ozone (O<sub>3</sub>), particulate matter (PM), and ultraviolet (UV) light have all been shown to induce skin damage through disruption of redox homeostasis and induction of pro-inflammatory status, resulting in an OxInflammation feedback. In the past few decades, several studies have been focused on the effect of pollution on cutaneous tissues, although very few have investigated the additive effects of different pollutants. We investigated the possible additive effect of the most represented pollutants in the environment in terms of skin oxinflammation, and whether topical application of an antioxidant mixture, containing 15% vitamin C, 1% vitamin E, and 0.5% ferulic acid could prevent the pollution-induced damage. 40 skin explants from 3 different human subjects were sequentially exposed to 200 mJ UV light, 0.25 ppm O<sub>3</sub> for 2 h, and 30 min of diesel exhaust particles, alone or in combination for a time course of 4 days. Our data showed a clear additive effect of ozone and particulates in combination with UV in increasing levels of several oxidative (4HNE, HO1, and AhR), inflammatory (COX2, NFκB), and loss of epidermis proteins such as Filagrin and Involucrin. Topical pretreatment with the mixture prevented the up-regulation of the inflammatory and oxidative markers and the loss of both Involucrin and Filagrin. In conclusion, the study suggests that daily application of a topical antioxidant compound is a useful approach to prevent pollution-induced skin damage.

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16041

**Efficacy of a nature-based lip treatment to repair dry damaged lips: Clinical and biophysical assessments**



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**Background:** Lip epithelium is characterized by a thin stratum corneum (SC) with incomplete corneocyte formation. Due to the lack of hair follicles and sweat glands, the lubricating effect of sebum is absent. As a result, the lips can easily become dry and chapped. Extremely dry and damaged lips require intensive treatment, which accelerate healing while providing moisturizing benefits. We investigated a nature-based lip treatment containing healing botanicals to improve barrier function, hydration, and overall health of the lips.

**Methods:** Lip properties in 45 healthy, female subjects (20-40 years) with moderate to severe dryness were studied. After a 3-day washout period of lip products, subjects used a nature-based lip treatment daily for 2 weeks. Barrier function (closed-chamber evaporimeter), hydration (cornometer) and clinical grading of healthy lip condition indicators (ie, scaling, cupping, cracking, fine lip lines, texture, and contour), were measured at baseline, and after day 3, week 1, and week 2 of product use.

**Results:** Visual examination showed statistically significant improvements in clinical grading of all parameters at all intervals. Lip hydration increased dramatically at day 3, with the increase consistent through week 2. TEWL was significantly reduced at week 1 and week 2, indicating improved lip barrier function. More than 90% of subjects reported favorably on various product attributes including improvement and acceptability of the product.

**Conclusions:** Nature-based lip treatment with botanicals is useful as treatment for restoring extremely dry, damaged lips.

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