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PII-028: NO PHOTOTOXICITY OR PHOTOALLERGY EFFECT WITH MRX-5LBT (10%) LIDOCAINE PATCH ADMINISTRATION

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Background:

An estimated 2% of marketed drugs induce phototoxic or photoallergic reactions. While photosafety testing is an infrequent assessment in drug development, clinical phototoxicity and photoallergy evaluations are required for dermal drugs that absorb UV/visible light (290-700 nm wavebands). Lidocaine is one such product that contains chromophores that absorb wavelengths >290 nm. Therefore, clinical photosafety testing was performed for MRX-5LBT (lidocaine topical system 10%), a patch indicated for the relief of pain associated with post-herpetic neuralgia.

Methods:

An open-label, evaluator-blinded, blank-controlled 2-part study was conducted to evaluate the phototoxicity and photoallergy potential of MRX-5LBT (lidocaine topical system 10%) in 88 healthy adult subjects with Fitzpatrick skin type I-III. In Part 1, dermal irritation (DI) was determined following 24 hours of test or blank patch application under non-irradiated and irradiated conditions for phototoxicity testing. A solar simulator was used to expose skin to UV wavebands. In Part 2, UV irradiated dermal assessment of the test or blank patch was examined during induction and challenge phases for photoallergy testing. DI was scored on a scale from 0 (no irritation) to 7 (strong reaction spreading beyond application site), and mean±SD was reported.

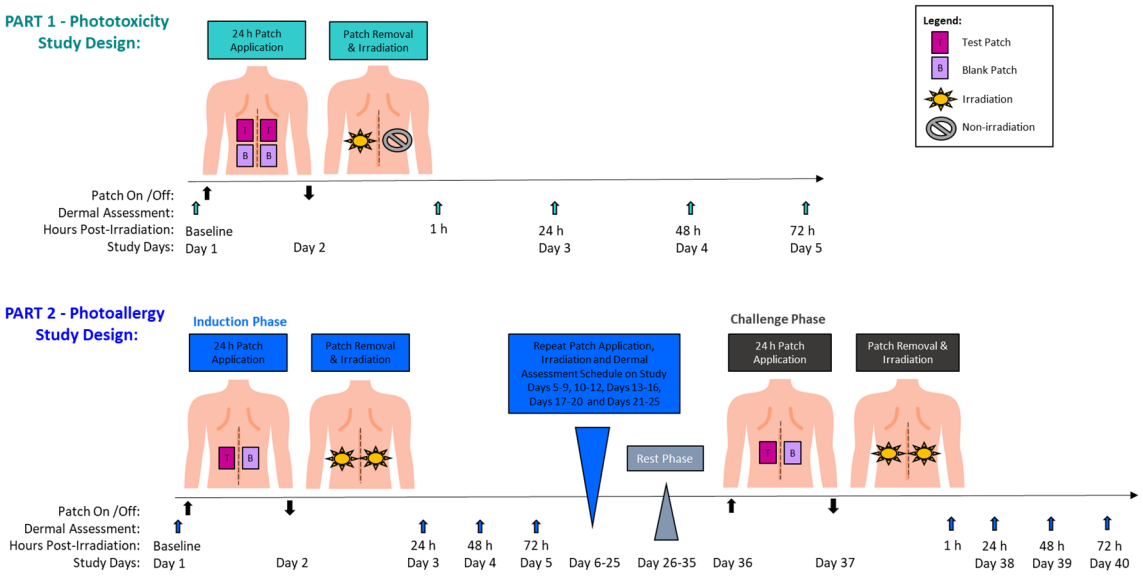
Results:

In Part 1, the maximum DI score observed was 1 (minimal erythema, barely perceptible) across all groups. Mean dermal response scores were 0.205±0.328 and 0.167±0.247 for the test patch under irradiated and non-irradiated conditions, respectively. The blank patch had slightly lower mean scores of 0.068±0.190 and 0.038±0.110, respectively. In Part 2, mean DI scores were similar between the test (0.953±0.260) and blank (0.932±0.247) patches during the induction phase, yet were greater overall when compared to the challenge phase (test: 0.250±0.315; blank: 0.176±0.277). No serious adverse events (AE) were reported. The most frequent AE was mild contact dermatitis (12%) in Part 1 and mild pruritus (16%) in Part 2.

Conclusion:

Phototoxicity potential of MRX-5LBT (lidocaine topical system 10%) following UV exposure was minimal and there was no evidence of photoallergy. Overall transdermal doses of MRX-5LBT (lidocaine topical system 10%) were well tolerated and does not pose a photosafety risk.

Study Design Figure: Phototoxicity and Photoallergy Study Design



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