No Photosafety or Photoallergy Effect with MRX-5LBT (10%) Lidocaine Patch Administration

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BACKGROUND

Clinical phototoxicity and photoallergy evaluations are required for topical drugs that absorb UV/visible light (290-700 nm). Lidocaine is one such product that contains chromophores that absorb wavelengths >290 nm. 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 (Part 1)** and **photoallergy (Part 2)** potential of MRX-5LBT (lidocaine topical system 10%) in 88 healthy adult subjects with Fitzpatrick skin type I-III.

- **Part 1:** Dermal irritation (DI) was determined following 24h of Test or Blank patch application under Irradiated and Non-Irradiated conditions.
- **Part 2:** DI assessment of Test or Blank patches were examined during an Induction phase (6 cycles of 24h patch application followed by UV irradiation and 5 day monitoring) and a Challenge phase (24h patch application to naïve site, UV irradiation and monitoring).

RESULTS

- **Part 1:** Max DI score was 1 for Test and Blank patches in either condition. Most participants had a DI=0, the Test patch had slightly more subjects with DI=1 compared to Blank patch.
- **Part 2:** Mean DI score was higher in Induction vs Challenge phase, yet similar in both conditions. In the Induction phase, the majority of subjects had D=1. Only, 4% and 2% of subjects had a DI of 3 and 2 with the Test patch, respectively; 2% had DI=2 with the Blank patch. No subject had a DI>1 during the Challenge phase.

SAFETY

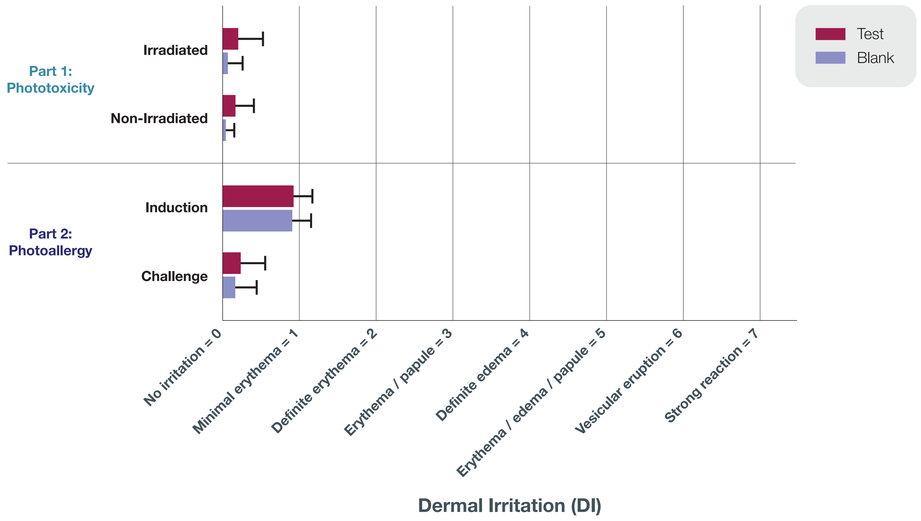
No serious adverse events (AE) were reported. The most frequent AE was mild contact dermatitis (12%) in Part 1 and mild pruritus (16%) in Part 2.

CONCLUSION

Overall transdermal doses of MRX-5LBT (lidocaine topical system 10%) patches were well tolerated and does not pose a photosafety risk.

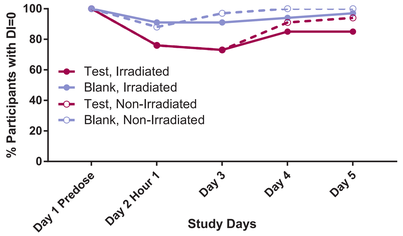
MRX-5LBT (lidocaine topical system 10%) has minimal phototoxicity potential and no photoallergy following UV exposure

Dermal Irritation Score for MRX-5LBT (lidocaine topical system 10%) Test & Blank Patches

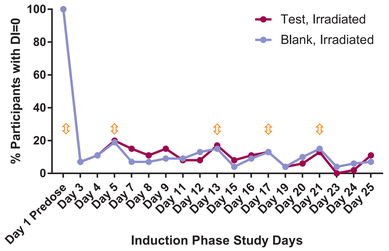


SCAN HERE FOR ABSTRACT AND STUDY DESIGN

Part 1: Phototoxicity

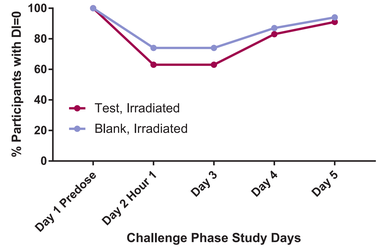


Part 2: Photoallergy - Induction Phase



⇕ Patch application for 24h followed by removal and irradiation

Part 2: Photoallergy - Challenge Phase



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