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Evaluation of the Irritation Potential of Three Topical Formulations of Minoxidil 2% Using Patch Test

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Abstract : Introduction: Minoxidil has been used topically for a long time to assist hair growth in the management of male androgenetic alopecia. The aim of this study was a comparative assessment of the irritation potential of three commercial formulations of minoxidil 2% topical solution in a human patch test. Methodology: The study was a non-randomized, double-blind, controlled, single-center study of 56 healthy adult Indian subjects. A 24-hour occlusive patch test was conducted with three formulations of minoxidil 2% topical solution. Products tested were aqueous-based minoxidil 2% (AnasureTM 2%, Sun Pharma, India – Brand A), alcohol-based minoxidil 2% (Brand B) and aqueous-based minoxidil 2% (Brand C). Isotonic saline 0.9% and 1% w/w sodium lauryl sulphate as a negative and positive control, respectively, were included. Patches were applied on the back, followed by removal after 24 hours. The Draize scale (0-4 points scale for erythema/dryness/wrinkles and for oedema) was used to evaluate and clinically score the skin reaction under constant artificial daylight 24 hours after the removal of the patches. The patch test was based on the principles outlined by Bureau of Indian Standards (BIS) (IS 4011:2018; Methods of Test for safety evaluation of Cosmetics-3rd revision). A mean combined score up to 2.0/8.0 indicates that a product is “non-irritant,” and a score between 2.0/8.0 and 4.0/8.0 indicates “mildly irritant” and a score above 4.0/8.0 indicates “irritant”. In case of any skin reaction that was observed, a follow-up was planned after one week to confirm recovery. Results: The 56 subjects who participated in the study had a mean age of 28.7 years (28 males and 28 females). The combined mean score ± standard deviation was: 0.09 ± 0.29 (Brand A), 0.29± 0.53 (Brand B), 0.30 ± 0.46 (Brand C), 3.25 ± 0.77 (positive control) and 0.02 ± 0.13 (negative control). This mean score of Brand A (Sun Pharma) was significantly lower than that of Brand B (p=0.016) and that of Brand C (p=0.004). The mean erythema score ± standard deviation was: 0.09 ± 0.29 (Brand A), 0.27 ± 0.49 (Brand B), 0.30 ± 0.46 (Brand C), 2.5 ± 0.66 (positive control) and 0.02 ± 0.13 (negative control). The mean erythema score of Brand A (Sun Pharma) was significantly lower than that of Brand B (p=0.019) and that of Brand C (p=0.004). Reactions that were observed 24 hours after patch removal subsided in a week’s time. Conclusion: Based on the human patch test as per the BIS, IS 4011:2018, all the three topical formulations of minoxidil 2% were found to be non-irritant. Brand A of 2% minoxidil (Sun Pharma) was found to be the least irritant than Brand B and Brand C based on the combined mean score and mean erythema score.

Keywords : erythema, irritation, minoxidil, patch test
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