

Evaluation of the Irritation Potential of Three Topical Formulations of Minoxidil 5% Using Patch Test

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Abstract : Minoxidil is used topically to help hair growth in the treatment of male androgenetic alopecia. The objective of this study is to compare irritation potential of three conventional formulation of minoxidil 5% topical solution of in human patch test. The study was a single centre, double blind, non-randomized controlled study in 56 healthy adult Indian subjects. Occlusive patch test for 24 hours was performed with three formulation of minoxidil 5% topical solution. Products tested included aqueous based minoxidil 5% (Anasure™ 5%, Sun Pharma, India - Brand A), alcohol based minoxidil 5% (Brand B) and aqueous based minoxidil 5% (Brand C). Isotonic saline 0.9% and 1% w/w sodium lauryl sulphate were included as negative control and positive control respectively. Patches were applied and removed after 24hours. The skin reaction was assessed and clinically scored 24 hours after the removal of the patches under constant artificial daylight source using Draize scale (0-4 points scale for erythema/wrinkles/dryness and for oedema). A combined mean score up to 2.0/8.0 indicates a product is “non-irritant” and score between 2.0/8.0 and 4.0/8.0 indicates “mildly irritant” and score above 4.0/8.0 indicates “irritant”. Follow-up was scheduled after one week to confirm recovery for any reaction. The procedure of the patch test followed the principles outlined by Bureau of Indian standards (BIS) (IS 4011:2018; Methods of Test for safety evaluation of Cosmetics-3rd revision). Fifty six subjects with mean age 30.9 years (27 males and 29 females) participated in the study. The combined mean score (\pm standard deviation) were: 0.13 \pm 0.33 (Brand A), 0.39 \pm 0.49 (Brand B), 0.22 \pm 0.41 (Brand C), 2.91 \pm 0.79 (Positive control) and 0.02 \pm 0.13 (Negative control). The mean score of Brand A (Sun Pharma product) was significantly lower than Brand B ($p=0.001$) and was comparable with Brand C ($p=0.21$). The combined mean erythema score (\pm standard deviation) were: 0.09 \pm 0.29 (Brand A), 0.27 \pm 0.5 (Brand B), 0.18 \pm 0.39 (Brand C), 2.02 \pm 0.49 (Positive control) and 0.0 \pm 0.0 (Negative control). The mean erythema score of Brand A was significantly lower than Brand B ($p=0.01$) and was comparable with Brand C ($p=0.16$). Any reaction observed at 24hours after patch removal subsided in a week. All the three topical formulation of minoxidil 5% were non-irritant. Brand A of 5% minoxidil (Sun Pharma) was found to be least irritant than Brand B and Brand C based on the combined mean score and mean erythema score in the human patch test as per the BIS, IS 4011;2018.

Keywords : erythema, irritation, minoxidil, patch test

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