

Ketoprofen 含有パップ剤先発-後発医薬品間の 貼付試験およびタック試験による比較検討

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Comparison of Cataplasms Containing Ketoprofen between Branded and Generic Products by a Patch Test and a Tack Test.

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Abstract

Objective: Substitutions from branded drugs to generic drugs are promoted, but very little information is available about equivalence of externally applied drugs.

Design: We performed a slant-ball tack test and a patch test to compare perceptions upon use as well as an adhesion property (tack) between branded (Mohrus) and three generic cataplasms: I (Touchron), II (Nicolol K), and III (Papen K), all containing ketoprofen.

Methods: Adhesive strength, elastic strength, and cold sensation associated with the cataplasms were graded as 1 to 5 in a patch test. The slant-ball tack test was performed according to Japanese industrial standards.

Results: Mean scores for cold sensation of generics I, II, and III were similar to that of branded cataplasm. Mean scores for adhesive strength of I, II, and III were 3.2, 3.2, and 3.0 respectively, while the mean score of the branded preparation was 3.8. Elastic strength of I, II, and III was scored as 3.2, 3.3, and 3.2 respectively, compare with the 4.3 for the branded drug. We confirmed I, II, and III to show less tack than branded drug in the slant-ball tack test.

Conclusion: Adhesive properties and perceptions upon use for cataplasms containing ketoprofen differed between a branded product and generic products. Our results should be of assistance in decision making by medical institutions as to adoption of generic cataplasm products.

Key words: generic drugs; ketoprofen; cataplasm; patch test; tack test