

<原 著>

**DS-2630 軟膏の血清コルチゾール値ならびに
一般臨床検査値に及ぼす影響の検討
－健常人を対象として0.064%ジプロピオン酸
ベタメタゾン軟膏との比較－**

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**Effects of DS-2630 Ointment on Serum Cortisol and
General Clinical Laboratory Examinations
－ Comparative Studies with 0.064% Betamethasone
Dipropionate Ointment in Healthy Volunteers －**

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Abstract

In an attempt to evaluate the safety of external application of DS-2630 ointment containing betamethasone dipropionate and sisomicin sulfate in human, we investigated the systemic effect of DS-2630 ointment by applying it in a single dose for 24 hrs and by the repeated application of 10 g for 14 hrs per day for 3 days. In the repeated application test, we used an ointment containing betamethasone dipropionate alone as a control.

The study was carried out on 19 healthy male volunteers, five of them were enrolled in the single application test while the remaining 14 were divided into 2 groups of 7 in the repeated application test for the group-to-group comparison.

In the single application test, application of DS-2630 ointment resulted in some reductions of serum cortisol levels but there was no significant difference from the baseline. In the repeated application test, application of both ointments resulted in reductions of serum cortisol levels, but they returned to the baseline immediately after the discontinuance; moreover, there was no significant difference between the two ointments neither before, during and after application nor throughout the recovery period.

Both of the single and the repeated application tests were associated with certain variations in findings of general clinical laboratory examinations, but they were all trivial, and none of them was clinically considered to be out of normal condition.

In the repeated application test with both ointments, folliculitis and acne occurred at the application sites.

Based on overall consideration of the above results, we concluded that the safety of DS-2630 ointment would be equal to that of the ointment containing betamethasone dipropionate alone.

Key words: DS-2630, Betamethasone dipropionate, Sisomicin sulfate, Serum cortisol, General clinical laboratory examinations