

Protocol for Dermex II Clinical Studies

NDA #20996 Topical Ointment

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Protocol procedure for Dermex II:

1. Biopsy when needed to verify diagnosis.
2. Photos before and after treatment.
3. Patient treated with Topical Dermex II using no more than 3 applications.
(One application was usually sufficient)
4. Post treatment biopsy.
5. Blind studies were performed on patients that were later treated with Dermex II.
 - a. This was done with the intention that the immuno- system would be the same in blind and actual studies.
 - b. Also this presented the same lesions and dermal conditions for both blind and actual studies.
6. The individual components were applied separately ZnCl₂, 8 Hydroxyquinoline and the base was also applied separately. The results were all negative.
7. All of the blind study patients were later treated with Dermex II with excellent results.
8. Over 100 patients were treated and the results were 100% effective.
9. Dermex II was found to be a great diagnostic aid. If applied to a suspicious lesion or area and the lesion or area was attacked and healed then it was of a serious nature. But if nothing visibly happened and there was no reaction then there was no serious involvement.

Conclusions:

Dermex II proved to be 100% effective with minimum inflammation. The area treated healed with little or no scarring. Dr. Jordan did a follow up of a number of patients treated and found no recurrence of any cancer.