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Doxycycline hyclate reduces comedones by 50 percent

Kapes, Beth A.

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Abstract (summary)

Dentists who regularly prescribe a 20-mg dose of Periostat for its anti-inflammatory role against periodontal disease reported their theory that doxycycline hyclate may also be effective against adult acne. With this hypothesis, the drug's manufacturer CollaGenex Pharmaceuticals, embarked on the placebo-controlled, double-blinded, sixmonth, 50 patient clinical trial to evaluate Doxycycline's efficacy in treating moderate acne.

Full Text

Newtown, Pa. - The subtherapeutic dosage of doxycycline hyclate tablets (Dermostat), 20 mg, is a valuable therapy against moderate acne while maintaining a somewhat independent stature from its antimicrobial affects, according to a multicenter clinical trial.

Doxycycline hyclate did reveal statistically significant benefits against each of the preestablished primary endpoints, including reducing total inflammatory lesions and total lesion counts. Most surprisingly, doxycycline hyclate appears to reduce the total number of comedones by 50 percent, the study's chair, Robert Skidmore, M.D., chief of dermatology, University of Florida Medical Center, said.

Dentists who regularly prescribe a 20-mg dose of Periostat for its anti-inflammatory role against periodontal disease reported their theory that doxycycline hyclate may also be effective against adult acne. With this hypothesis, the drug's manufacturer CollaGenex Pharmaceuticals, embarked on the placebo-controlled, double-blinded, sixmonth, 50 patient clinical trial to evaluate Doxycycline's efficacy in treating moderate acne. Rodney Kovach, M.D., chief of dermatology, West Virginia University Health Sciences Center, also conducted the study.

"While I was initially skeptical of the drug effectively addressing each of the endpoints - especially the anticipated goal of reducing overall comedones - we did find this pilot study to show Dermostat's effectiveness on all levels," Dr. Skidmore said. "There were very few side effects, in addition to showing an absence of photosensitivity a side effect seen in many acne therapies."

Dr. Reddy's Laboratories, Ltd., et al.
v.
Galderma Laboratories, Inc.
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Exhibit 1015

Dr. Skidmore said the study clearly illustrates the potential clinical benefit of Dermostat in the management of inflammatory acne, while showing no bacterial resistance in its submicrobial dosage.

The most compelling evidence that the long-term, low-dose therapy may be beneficial for the treatment of acne was presented in the data analysis confirming no evidence of an antimicrobial effect, changes in resistance profiles on the skin flora, or cross-resistance to other antibiotics when compared with placebo.

While discussions with the FDA for approval of doxycycline hyclate tablets as Dermostat are planned for this fall, and patent applications have been filed with the U.S. Patent and Trademark Office, Dr. Skidmore contended that patients with moderate acne could gain benefit from the drug now.

"Periostat was approved by the FDA in 1998, and it could currently be used for its anti-inflammatory benefits with excellent results," Dr. Skidmore said. "Dermatologists should see from this study that Dermostat appears to be a relatively innocuous therapy that can be administered long-term with potentially few side effects." DT

AuthorAffiliation

By Beth A. Kapes

Staff Correspondent

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