Extina Is No-Go for Seborrheic Dermatitis

BY ROBERT FINN
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Extina, a formulation of 2% ketoconazole in a proprietary foam vehicle, has been deemed nonapprovable for seborrheic dermatitis by the U.S. Food and Drug Administration.

The FDA's Nov. 23, 2004, letter concluded that Extina was not approvable because a clinical trial showed that the drug was no better than the placebo foam alone.

On the other hand, the same phase III trial did show that Extina was statistically equivalent to Nizoral (2% ketoconazole in a cream base).

"The FDA's decision is disappointing and surprising," said Thomas G. Wiggans, chief executive officer of Connetics Corp. (Palo Alto, Calif.), in a prepared statement.

"Based on discussions with the FDA regarding the requirements for the phase III trial, we believe Extina met the study end points and that the [new drug application] was approvable. We believe that Extina demonstrated efficacy and warranted approval. However, under the circumstances, we will evaluate all options for Extina."

The company plans to discuss the nonapprovable letter with the FDA.

According to the company statement, Connetics may conduct another clinical trial, or it may choose to abandon the product in favor of concentrating on other, more promising candidates in its pipeline. ■

VERBATIM

'This "back fat" causes obvious and unattractive bumps and ripples underneath clothing.'

Dr. Naomi Lawrence, on a postmenopausal phenomenon that can be addressed with tumescent liposuction, p. 10.

Community-Acquired MRSA Hit L.A. Children

WASHINGTON — A clonal outbreak of community-acquired methicillin-resistant *Staphylococcus aureus* in Los Angeles County led to a high rate of hospitalizations among children in 2003, Elizabeth Bancroft, M.D., reported in a poster at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

Following four skin infection outbreaks due to a particular clone of MRSA (USA 300; ST:8) in 2002, the Los Angeles County Department of Health Services made community-acquired methicillin-resistant *S. aureus* (CAMRSA) infections in hospitalized children less than 18 years of age a reportable condition for 6 months during 2003. A total of 140 cases were reported between May 5 and Nov. 7, said Dr. Bancroft of the county health department.

Mean age of the children was 6.25 years (range 0-17), 51% were female, 66% were Hispanic, 16% white, 15% black, and the remainder said they were "other." Their mean length of stay was 5.13 days (range 1-30). Diagnoses included cellulitis in 44%, abscess in 36%, and a combination of the two in 11%.

In 23%, chart notes indicated a misdiagnosis of possible insect or spider bites, and 75% of the total 135 who had been treated with antibiotics were initially treated inappropriately with β-lactams, she said at the conference, sponsored by the American Society for Microbiology.

Among 82 for whom a caregiver was interviewed, 24 (29%) had a household contact with a skin infection within a month of the child's infection.

Other nosocomial risk factors were present in 29 (35%), while risk factors for community-acquired infection were present in 38 (46%), including 9 (11%) who had contact with a recently incarcerated person.

Of 83 isolates analyzed, 79 (96%) were consistent with the USA 300; ST:8 CAMRSA genotype, even though many of the children had nosocomial risk factors. During the 6 months, the 140 pediatric CAMRSA cases in Los Angeles far outnumbered other common reportable diseases, including salmonella (99) and invasive pneumococcal disease (84), she noted.

—Miriam E. Tucker