## Control Vulvar Lichen Sclerosus to Cut Ca Risk

BY KATE JOHNSON Montreal Bureau

HOUSTON — Controlling the intense pruritus of vulvar lichen sclerosus is important, not only for patients' quality of life, but also to reduce their risk of developing cancer, according to several experts at a conference on vulvovaginal diseases jointly sponsored by Baylor College of Medicine and the Methodist Hospital.

It is estimated that between 3% and 5% of untreated patients with vulvar lichen sclerosus will develop vulvar carcinoma in the following 10-20 years, said Dr. Raymond H. Kaufman, professor emeritus in obstetrics, gynecology, and pathology at Baylor College of Medicine, Houston. That compares to an annual incidence of vulvar carcinoma of 1 in 150,000 (0.0006%) in the general population. "There is an increased risk [in patients with lichen sclerosus], and even though it is small, these patients should be warned," he said. "Generally, it's the noncompliant patients, or the scratchers, who are most at risk." In fact, between 50% and 80% of patients with vulvar cancer have a history of lichen sclerosus, he said.

This condition is itchy, itchy, itchy," agreed Dr. Libby Edwards, a dermatologist who has a private practice in Charlotte, N.C. Poor control can also result in excoriations and secondary infections in many patients, she said in an interview.

A review by Dr. Kaufman found that in 88% of his patients, the clinical appearance of the vulvar skin was white and crinkled, with thickening of the skin in 38%, fissures in 30%, and phimosis in 23%. "The labia minora may fuse with the labia majora, and the tissue is easily traumatized," said Dr. Kaufman. "Areas of ecchymosis



Typical lichen sclerosus shows a white plaque with parchment-like texture.



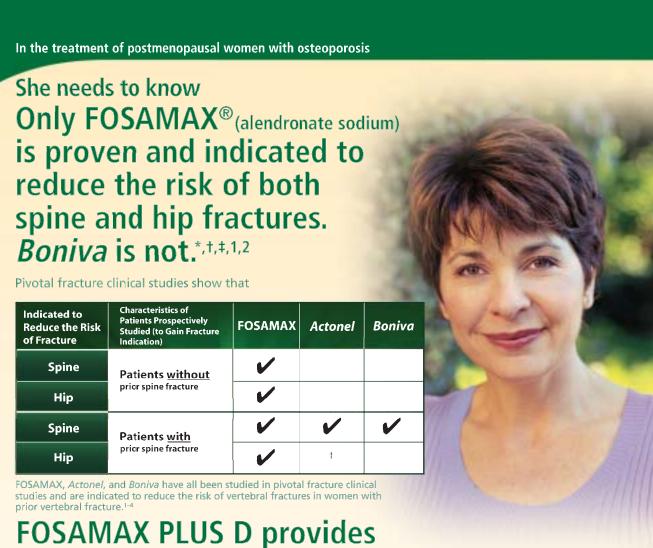
Advanced disease can cause loss of the labia minora and scar the clitoral hood.

are very common and can cause anxieties about melanoma.'

Both experts noted that testosterone cream, once thought to be an effective treatment for lichen sclerosus, is now considered no better than placebo. Dr. Kaufman recommends clobetasol ointment 0.05%, twice daily for 2 months, at bedtime for the next 2 months, and then every other day for 2 months—with a maintenance regimen of once or twice weekly or according to symptoms.

Dr. Edwards said she also recommends starting treatment with clobetasol ointment twice daily but reevaluates monthly. "Without monthly follow-up, patients often stop using the medication because their symptoms go away, and I want to monitor them for improvement and possible side effects with this very potent steroid." When the skin texture becomes normal, she reduces the dosage to once daily three times per week. When patients are on this regimen, she said, followup visits are necessary only at 6-month intervals to assess for recurrence, side effects, or signs of cancer.

For those patients who do not respond to clobetasol, Dr. Kaufman recommends Elidel 1% or Protopic 0.1% cream twice a day, but he advises caution because these creams can cause significant vulvar irritation. In such cases, it may be necessary to titrate the dosage down to once a day or even every other day until the patient becomes more comfortable, he said.



## FOSAMAX PLUS D provides

 Confidence in knowing that your patients are offered at least the minimum vitamin D intake recommended by guidelines.

FOSAMAX and FOSAMAX PLUS D are contraindicated in patients with esophageal abnormalities which delay esophageal emptying (eg, stricture or achalasia) and in patients unable to stand or sit upright for at least 30 minutes. Patients at increased risk of aspiration should not receive FOSAMAX oral solution. FOSAMAX and FOSAMAX PLUS D are contraindicated in patients with hypersensitivity to any component of these products and in patients with hypocalcemia (see PRECAUTIONS). FOSAMAX and FOSAMAX PLUS D, like other bisphosphonates, may cause local irritation of the upper gastrointestinal mucosa.

- \* The Fracture Intervention Trial (FIT) consisted of 6.459 women in 2 arms, the Vertebral Fracture Arm (VFA) (3 years), and the Clinical Fracture Arm (CFA) (4 years). In both arms of the study, women were randomized to either placebo or FOSAMAX 5 mg Once Daily for the first 2 years and FOSAMAX 10 mg Once Daily for the remainder of the trial. In the FIT VFA, 2,027 women (mean age = 71 years) with preexisting vertebral fractures were studied for 3 years. In the FIT CFA, 4,432 women (mean age = 68 years) with no preexisting vertebral fracture and femoral neck bone mineral density T-score ≤=1.6 (after National Health and Nutrition Examination Survey (INHAMSE) adjustment) at baseline were studied for a duration of 4,25 years. The primary end point of the FIT VFA was vertebral fracture, and the primary end point of the FIT CFA was any clinical (symptomatic) fracture. A relative risk reduction of 47% (7.1% absolute risk reduction) was seen in the primary end point in the FIT VFA.<sup>3,2</sup>

  \* The Vertebral Efficacy With Risedronate Therapy (VERT) trials prospectively studied risedronate vs placebo in patients with osteoporosis who had at least 1 prior vertebral fracture at entry. Based on these trials, Actone/ is also indicated to reduce the incidence of a composite end point of nonvertebral osteoporosis-related fractures.¹

  \* The Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe
- The Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe (BONE) prospectively studied oral ibandronate administered either daily or intermittently vs placebo in patients with osteoporosis who had between 1 and 4 prevalent vertebral fractures at entry.<sup>2</sup>

References: 1. Actonel [package insert]. Cincinnati, Ohio: Procter & Gamble Pharmaceuticals, 2006. 2. Boniva [package insert]. Nutley, NJ: Roche Laboratories Inc; 2006. 3. Black DM, Cummings SR, Karpf D, et al, for the Fracture Intervention Trial Research Group. Randomised trial of effect of alendronate on risk of fracture in women with existing vertebral fractures. Lancet. 1996;348:1535–1541. 4. Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package DA-FOS73(4).

Please read the Brief Summary of Prescribing Information on the adjacent page For product information about FOSAMAX and FOSAMAX PLUS D, please visit fosamaxplusd.cc For services and resources on Merck products, log on to

FOSAMAX is a registered trademark of Merck & Co., Inc. FOSAMAX PLUS D is a trademark of Merck & Co., Inc. Other brands listed are the trademarks of their respective owners and ar not trademarks of Merck & Co., Inc.



MERCK Copyright © 2007 Merck & Co., Inc. All rights reserved. 20701358(1)(602)-FOS