Summer Comeback Seen for Contraceptive Sponge

BY ELIZABETH MECHCATIE
Senior Writer

More than a decade after it was taken off the market because of manufacturing issues, the contraceptive sponge has been cleared by the Food and Drug Administration and is expected to be available this summer.

The Today Sponge, which is made of polyurethane foam and contains a 1-g reservoir of nonoxynol-9, will be available over the counter this summer, according to Allendale Pharmaceuticals Inc., the N.J.-based company that bought the rights to the product in 1998. It is the same device taken off the market in 1994, when safety issues were raised with the facilities where the sponge was manufactured.

One sponge, which provides a barrier between the cervix and sperm, continually releases 125-150 mg of nonoxynol-9 into the vagina and can be used for 24 hours, the company said. The polyurethane foam "traps and absorbs semen" before the sperm are able to enter the cervix. It must be left in place for at least 6 hours after the last act of intercourse, and it does not protect against sexually transmitted diseases, the company said.

In multicenter clinical trials of more than 1,800 women conducted in the United States and eight other countries before the device was pulled from the market, the sponge was 89% effective in preventing pregnancies during 1 year among 939 parous women studied and 91% effective among 915 nulliparous women studied, when used properly for every act of intercourse, according to the company. When used improperly and inconsistently, the effectiveness rate ranged from 84%-87%, the company said.

Use of the Today Sponge is contraindicated in individuals who are allergic or sensitive to nonoxynol-9. Typical symptoms can include vaginal burning, itching, redness, rash, and irritation. In the U.S. portion of the clinical study, 4% of women discontinued use of the sponge due to allergic symptoms. Worldwide, this figure was 2.1%. If the user or her partner is allergic to sulfa drugs, he or she should consult a physician before using the sponge.

The sponge is contraindicated for use during menstruation. Some cases of nonmenstrual toxic shock syndrome have been reported in women using barrier contraceptives, including Today Sponge, the diaphragm, and the cervical cap. ■

St. John's Wort May Not Curb OC Effectiveness

Los Angeles — St. John's wort does not appear to interfere with the antiandrogenic effects of oral contraceptive pills, Robin Fogle, M.D., said at the annual meeting of the Society for Gynecologic Investigation.

She said testosterone levels decreased, while a marker of androgen metabolism increased, in 15 healthy women treated with St. John's wort and Loestrin 1/20 (norethindrone/estradiol) in a 4-month study.

Although the changes did not reach statistical significance, the outcomes strongly suggest St. John's wort will not interfere with the pill's effects when used as a primary treatment for hirsutism, said Dr. Fogle, of the University of Southern California, Los Angeles, in an interview.

The study was undertaken because reports have shown the over-the-counter herbal remedy, commonly used for depression and inflammation, induces cytochrome P450 activity. This can interfere with the efficacy of some drugs, including oral contraceptives, Dr. Fogle and her coinvestigators wrote in a poster presented at the meeting.

None of the women in the study had hirsutism. They took Loestrin 1/20 for four consecutive 28-day cycles. During the last two cycles, the protocol added 300 mg of St. John's wort taken three times daily.

Mean testosterone fell 10.7% (from 44.8 ng/dL to 40.0 ng/dL), and free testosterone fell 15.8% (from 0.38 ng/dL to 0.32 ng/dL) after the addition of St. John's wort. Conversely, 3α-androstanediol glucuronide, the marker of androgen metabolism, rose 6.5% from 2 ng/mL to 2.13 ng/mL.

"It appears that St. John's wort enhances androgen metabolism and does not interfere with the antiandrogenic properties of oral contraceptive pills," they said.

—Jane Salodof MacNeil

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