



Wednesday, April 18, 2007

**Wyeth Comments on Report on Hormone Therapy and Ovarian Cancer
from the Million Women Study in *The Lancet***

***- Reported Potential Risk is Small and Included in Class Labeling for
Hormone Therapy -***

A report from the Million Women Study, an observational study of women in the United Kingdom, suggests a small, but statistically significant, increase in ovarian cancer risk among women taking hormone therapy. This report was released online today and will be included in the April 21, 2007 issue of *The Lancet*.

Findings from this study and other studies suggest the elevation of ovarian cancer risk is associated with higher cumulative doses of hormone therapy due to either a longer duration of therapy (more than 10 years) and/or higher doses. Current practice recommendations call for the lowest effective dose for the shortest duration necessary to achieve the desired clinical effect.

Other published results from studies evaluating the potential relationship between hormone therapy use and ovarian cancer risk have been inconsistent. However, it is important to note that the potential risk of ovarian cancer, while small, is included in the class labeling for hormone therapy. The information contained in product labeling is primarily based on the estrogen plus progestin findings of the largest prospective study, the Women's Health Initiative (WHI).

“Hormone therapy remains a good health care choice for the appropriate woman seeking the relief of moderate to severe menopausal symptoms, including hot flashes, night sweats and vaginal atrophy, and the prevention of postmenopausal osteoporosis,” says Joseph Camardo, M.D., Senior Vice President of Global Medical Affairs for Wyeth Pharmaceuticals.

Wyeth continues to encourage women to speak with their health care professional to determine what treatment options for their menopausal symptoms are most appropriate based upon their individual circumstances and risk profile.



What is the most important information you should know about PREMARIN[®] (estrogens) or PREMPRO[®] (a combination of estrogens and a progestin)?

- **Estrogens increase the chances of getting cancer of the uterus.**
- **Report any unusual vaginal bleeding right away while you are taking these products. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your health care provider should check any unusual vaginal bleeding to find out the cause.**
- **Do not use estrogens with or without progestins to prevent heart disease, heart attacks, strokes or dementia.**

Using estrogens with or without progestins may increase your chances of getting heart attacks, strokes, breast cancer and blood clots. Using estrogens, with or without progestins, may increase your risk of dementia, based on a study of women aged 65 years or older. You and your health care provider should talk regularly about whether you still need treatment with estrogens.

PREMARIN[®] (conjugated estrogens tablets, USP) is used after menopause to reduce moderate to severe hot flashes; to treat moderate to severe dryness, itching and burning in and around the vagina; and to help reduce your chances of getting osteoporosis (thin weak bones).

PREMPRO[®] (conjugated estrogens/medroxyprogesterone acetate tablets) is used after menopause in women with a uterus to reduce moderate to severe hot flashes; to treat moderate to severe dryness, itching and burning in and around the vagina; and to help reduce your chances of getting osteoporosis (thin weak bones).

PREMARIN and PREMPRO should be used at the lowest effective dose and for the shortest duration consistent with your treatment goals and risks. If using PREMARIN or PREMPRO only to treat your symptoms of vaginal dryness, consider topical therapies first. If you do not have symptoms, non-estrogen treatments should be carefully considered before taking PREMARIN or PREMPRO solely for the prevention of postmenopausal osteoporosis.

In a clinical trial, the most commonly reported ($\geq 5\%$) side effects that occurred more frequently with PREMARIN than with placebo were vaginitis due to yeast or other causes, vaginal bleeding, painful menstruation and leg cramps.



In a clinical trial, the most commonly reported ($\geq 5\%$) side effects that occurred more frequently with PREMPRO 0.45 mg/1.5 mg and PREMPRO 0.625 mg/2.5 mg than with placebo were breast pain/enlargement, vaginitis due to yeast or other causes, leg cramps, vaginal spotting/bleeding and painful menstruation. In a clinical trial, there was no difference in the commonly reported ($\geq 5\%$) side effects for women taking PREMPRO 0.3 mg/1.5 mg compared with those taking placebo.

PREMARIN and PREMPRO should not be used if you have unusual vaginal bleeding, have or had cancer of the breast or uterus, had a stroke or heart attack in the past year, have or had blood clots, have liver problems, are allergic to any of the ingredients in PREMARIN or PREMPRO, or think you may be pregnant. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.

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