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Wyeth®

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FDA Approves Prescribing Information for Postmenopausal Hormone Therapies

Dear Health Care Professional:

We are writing to inform you that Wyeth, in close cooperation with the U.S. Food and Drug Administration (FDA), has adopted new labeling for Prempro™ (conjugated estrogens/medroxyprogesterone acetate tablets), Premphase® (conjugated estrogens/medroxyprogesterone acetate tablets), and Premarin® (conjugated estrogens tablets, USP). A copy of the new Prescribing Information is enclosed and is available at www.premarin.com and www.prempro.com.

The labeling changes include a boxed warning, which states that estrogens and estrogens plus progestin therapies should not be used for the prevention of cardiovascular disease. The boxed warning for estrogen-only therapies includes this same language as well as the long-recognized advisory that estrogens increase the risk of endometrial cancer when used without a progestin.

The boxed warning also includes risk information that previously appeared in other sections of the labeling. Specifically, it states that because the Women's Health Initiative (WHI) study reported an increased risk of myocardial infarction, stroke, invasive breast cancer, and venous thromboembolism (VTE), estrogens and estrogens plus progestin therapies should be prescribed for the shortest duration consistent with treatment goals. The boxed warning also states that because other combinations of estrogens and progestins were not studied in the WHI, in the absence of comparable data, the risks identified in the study should be assumed to be similar for all postmenopausal hormone therapy (HT) products.

The FDA is contacting other manufacturers of HT products to urge them to implement similar revisions to the prescribing information for their products.

Prempro and Premarin are indicated for:

- Relief of moderate to severe vasomotor symptoms associated with menopause (the primary reason women seek treatment)
- Relief of moderate to severe symptoms of vulvovaginal atrophy associated with menopause
- Prevention of postmenopausal osteoporosis in appropriately selected patients

When used in women without menopausal symptoms for the prevention of postmenopausal osteoporosis, HT should be used only in women at significant risk for osteoporosis in whom non-estrogen therapies have been carefully considered.

Only postmenopausal HT is indicated for all three of these conditions. Premarin and Prempro continue to be valuable treatments for symptomatic menopausal women.

Please see accompanying Prescribing Information. If you have any questions, please contact Global Medical Affairs at 1-800-934-5556. Thank you for your attention to this important information.

Sincerely,

Victoria Kusiak

Victoria Kusiak, M.D.
Vice President, Global Medical Affairs and
North American Medical Director

Enclosures

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