

Informed Consent for Combination Estrogen-Progestin Hormone Replacement Therapy

I wish to take hormone replacement therapy that uses a combination of two drugs, estrogen and progestin. I have discussed the use of these drugs with my physician. Although these drugs have been used for many years, my physician has given me information about a recent study that quantified certain health risks in using this combination of drugs. I have decided to use these drugs and have accepted the risks of combination estrogen-progestin hormone replacement therapy (HRT).

My doctor has given me a summary of the recent study on HRT. I know that in this study, the Women's Health Initiative (WHI), found that women taking a combination of estrogen and progestin had more cases of heart attacks, strokes, blood clots, and breast cancer than women who did not take these drugs. The study also found that there were fewer cases of colorectal cancer and hip fractures in women who took these drugs compared to women who did not. The study also recommended that women not take these drugs for prevention of heart disease.

Although the WHI study only involved a specific formulation of these drugs, I must assume the results apply to other formulations used for hormone replacement therapy. Other studies are being done, and I agree to visit my doctor annually to monitor my health and to learn about other studies on these drugs. My doctor has also told me about some of the options that may be used for my care. It is my decision to use hormone replacement therapy at this time. I may decide to stop using these drugs at any time.

The following "boxed warning" is contained in the Prempro product labeling, courtesy of Wyeth:

Warning:

Estrogens and progestins should not be used for the prevention of cardiovascular disease. The Women's Health Initiative (WHI) reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women during 5 years of treatment with conjugated equine estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg) relative to placebo. Other doses of conjugated estrogens and medroxyprogesterone acetate, and other combinations of estrogens and progestins were not studied in the WHI and, in the absence of comparable data, these risks should be assumed to be similar. Because of these risks, estrogens and progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with the treatment goals and risks for the individual woman.

Patient

Date

Facts for Women Considering Hormone Replacement Therapy With Estrogen and Progestin

This Fact Sheet is being given to you because you are considering using two drugs, estrogen and progestin, for what is called hormone replacement therapy (HRT). These drugs have been used for many years to help women with symptoms of menopause, and, for many years, these drugs were considered to be safe for women and to have acceptable risks. However, a large prospective study called the Women's Health Initiative (WHI) found that these drugs have certain risks that should be considered before deciding whether and how to use them.

- The WHI study found that the combination of estrogen plus progestin drugs did not prevent heart disease as had been thought for many years.
- In addition, the WHI study reported that women taking the combination of drugs had the following risks and benefits:

Risks - for every 10,000 women who took the drugs:

- 38 developed breast cancer compared to 30 not taking the drugs
- 37 had a heart attack compared to 30 not taking the drugs
- 29 had a stroke compared to 21 not taking the drugs
- 34 had blood clots compared to 16 not taking the drugs

Benefits - for every 10,000 women who took the drugs:

- 10 had hip fractures compared to 15 not taking the drugs
- 10 developed colon cancer compared to 16 not taking the drugs

The WHI study left many questions unanswered, and women should discuss health care options and questions with their doctor. Some examples of unanswered questions are: 1) the extent to which the risks and benefits seen in this study apply to women who don't fit the characteristics of the population being studied (where the average age was 63), 2) the risks and benefits of using these drugs for a short period of time, and 3) the risks and benefits of taking estrogen by itself. Regarding the woman who no longer has a uterus and is taking only estrogen, the WHI study is ongoing. Package inserts with new information on Prempro/Premphase and Premarin are available online at the Wyeth website, www.wyeth.com/content/ShowFile.asp?id=133.

Hormone replacement therapy is still an option for treating health conditions related to menopause, and each woman's condition is different. If you decide to use HRT, you should report to your doctor for an annual physical. Many doctors recommend taking HRT in small doses and using these drugs for as short a time as possible. Although there is no data on the effect of doing this, it is also recommended that women may want to stop using hormones from time to time to see if health conditions related to menopause may have subsided or may be controlled without these drugs or with other drugs. Questions should be discussed with your doctor so that you can make an informed decision regarding using these drugs.