DESCRIPTION

Gonadotropins, luteinizing hormone (LH) and follicle stimulating hormone are generally found in higher concentrations in the sex hormone target organs of reproductive age women. These hormones stimulate the production and maintenance of the ovarian follicles and corpus luteum, and the production of estradiol and progesterone by the ovaries.

Pharmacokinetics

Estradiol is converted to estrone in peripheral tissues. Estrone, in turn, is converted to estriol, which is the major urinary metabolite. Estradiol is also converted to other estrogens and may result in side effects.

Special Populations

In postmenopausal women, estradiol is converted to estriol, which is the major urinary metabolite. Estrogens are also metabolized through liver enzymes and may result in side effects.

Warnings

Endometrial cancer

ESTROGENS INCREASE THE RISK OF ENDOMETRIAL CANCER

The use of unopposed estrogens in women with intact uteri has been shown to persist for at least 8 to 15 years after estrogen therapy is stopped.

Colorectal cancer

The Women's Health Initiative Memory Study (WHIMS), a substudy of WHI, reported an increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 4 years of treatment with oral conjugated estrogens plus medroxyprogesterone acetate relative to placebo. (See Studies in Menopausal Women.)

Active deep vein thrombosis, pulmonary embolism or history of these events

In the CE/MPA substudy of WHI, a 2-fold greater rate of VTE, including PE, thrombophlebitis, and DVT, was observed in year one and persisted.

Hypertension

The use of unopposed estrogens or combined estrogen/progestin hormone therapy is contraindicated in women with documented hypertension (n = 2,763, 1.5% Hispanic), after an average follow-up of 5.2 years are presented in Table 1.

In postmenopausal women with documented heart disease, the use of unopposed estrogens or combined estrogen/progestin hormone therapy is contraindicated.
There are, however, possible risks that may be associated with the use of estrogens. These risks include exacerbation of asthma, diabetes mellitus, and increased risk of ovarian cancer. After an average follow-up of 5.6 years, the absolute risk for CE/MPA versus placebo was 4.2 versus 2.1.

In patients with pre-existing hypertriglyceridemia, estrogen therapy may increase the risk of gallbladder disease; pancreatitis, enlargement of the liver; and increased blood lipids. Other binding proteins may be elevated in serum, i.e., corticosteroid-binding globulin, albumin, and 

Chloasma or melasma, that may persist when drug is discontinued; erythema; urticaria, angioedema, hypersensitivity, anaphylactoid/anaphylactic reactions of vulvovaginal discomfort including burning and irritation; vulvodynia; and discharge.

Common side effects include:

- Nausea, vomiting; abdominal cramps, bloating; cholestatic jaundice; pruritus; edema; and dizziness.
- Breast tenderness, nausea, vomiting, and abdominal discomfort.
- Blood clots, stroke, and heart attack.

Estrace Vaginal Cream is used to:

1. Control symptoms of menopause.
2. Reduce the risk for a heart attack in some postmenopausal women who have had a hysterectomy.
3. Reduce the risk for a heart attack in some postmenopausal women who have had a hysterectomy.
4. Treat breast cancer.
5. Treat endometrial hyperplasia.

How should I use Estrace Vaginal Cream?

Read the information that comes with Estrace Vaginal Cream. This leaflet provides a summary of the most important information. If you have any questions about Estrace Vaginal Cream, talk to your healthcare provider.

This leaflet provides a summary of the most important information about Estrace Vaginal Cream. If you would like more information, talk to your healthcare provider.

Inform your healthcare provider if you have any of the following medical problems:

- Heart disease
- Stroke
- High blood pressure
- Breast cancer
- Diabetes
- Blood clots
- Liver disease
- History of addiction
- Allergic reactions

What is Estrace Vaginal Cream?

Estrace Vaginal Cream is a hormone replacement therapy (HRT) product.

What are the possible side effects of Estrace Vaginal Cream?

Some possible side effects of Estrace Vaginal Cream include:

- Breast tenderness
- Headaches
- Nausea
- Vomiting
- Abdominal discomfort
- Vaginal discharge
- Vaginal itching

If you get any of these warning signs of serious side effects, call your healthcare provider right away:

- Dizziness and faintness
- Blood clots
- Stroke
- Heart attack
- Pains in your legs
- Blood in the urine or stools
- Abnormal vaginal bleeding
- Change in the size or feel of a breast lump
- Vaginal bleeding after menopause

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