5. Hypercalcemia.

4. Elevated blood pressure.

3. Treatment of hypoestrogenism due to hypogonadism, castration or prior oophorectomy, or hypogonadism in men treated with gonadotropin-hormone releasing hormone (GnRH) agonists. Estrogen has a high intrinsic potency that results in limited oral potency. By contrast, polacrilin potassium is used in suppository form to enhance progestin absorption and effectiveness. Estrogen drug products administered via suppository (e.g., estradiol and estriol) result in a reservoir for the formation of more active estrogenic species. A certain equilibrium of circulating conjugated and unconjugated estrogenic forms occurs. Estradiol isomers, changes in the epiphyses of the long bones that allow for the pubertal growth spurt and maintenance of bone density, stromal development, and the accretion of fat. Estrogens are important in the development and maintenance of the uterus, cervix, and vagina. With other hormones, such as pituitary hormones and progesterones, they act on specific targets.

2. Treatment of moderate to severe vasomotor symptoms associated with menopause. The symptoms of menopause, including hot flashes and night sweats, can be relieved by estrogen replacement therapy (ERT). Estrogen replacement therapy reduces bone resorption and retards the rate of bone loss typically associated with menopause. The risk factors for developing osteoporosis, which includes low bone mass, decreases in estrogen levels, and an increase in bone turnover. Women are at higher risk than men because they start menopause earlier and have a longer life expectancy. They lose bone at a faster rate in the years immediately following menopause, and the rate of bone mass decline is accelerated. Women who start estrogen replacement within a few years of menopause tend to have increased coagulation parameters at baseline compared to women who begin treatment later. Estrogen replacement therapy may increase the risk of thromboembolic disease, which is associated with increased coagulation parameters. The importance of these data points is that estrogen replacement therapy and reduction of cardiovascular disease in women who are at increased risk or who have a risk factor for developing osteoporosis is a contentious issue.

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Estradiol tablets are indicated in the treatment of moderate to severe vasomotor symptoms associated with menopause. As a general principle, the administration of any hormone should be guided by the lowest effective dose necessary for the treatment of the condition being treated.

C. Laboratory Tests.

D. Dosage and Administration.

E. Nursing Mothers.

F. Geriatric Use.

G. Contraindications.

H. Precautions.

I. Adverse Reactions.

J. Drug Interactions.

K. Overdosage.

L. Incompatibilities.

M. Storage and Handling.

N. Package Insert.


4. May protect women against developing heart disease. However, this is not

Watson Laboratories, Inc. Revised May 4, 2000

Estrogens increase the risk of developing a condition (endometrial

If you want to know which of these possible uses are approved for the

your doctor to be sure you are using the lowest possible dose that works,

WATSON 488:

Estradiol Tablets, USP 2 mg; round, light green scored tablets imprinted

WATSON 487:

WATSON 528:

Estradiol Tablets, USP 0.5 mg; round, white scored tablets imprinted with

1. For treatment of moderate to severe vasomotor symptoms, vulval

bleeding may occur in females.

large doses of estrogen-containing oral contraceptives by young children.

2. For treatment of female hypoestrogenism due to hypogonadism,

ods). If both ovaries are removed during an operation before natu-

promenopausal and premenopausal symptoms. Estrogen and progestins may

result in a missed period. For this reason, it is important to follow your doctor's

treatment instructions carefully. If you do not bleed in the expected

period, or if you experience any unusual bleeding, contact your doctor

immediately.


• Nausea and vomiting.

• Change in amount of cervical secretion.

• Loss of scalp hair.

• Chloasma or melasma which may persist when drug is discontinued.

• Edema.

• Increase or decrease in weight.

• Chorea.

• Abnormal bleeding from the vagina (possible uterine cancer)

• Cancer of the breast.

• If you have had cancer.

• If you are breastfeeding, you should avoid using any drugs

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