

Information For the User

Estradiol (2mg)

Ezendiol Tablet

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Composition:

Each tablet contains:

- Estradiol: 2 mg

Pharmacological Class:

- Estradiol: Estrogen Hormone

Indications:

Estradiol 2 mg tablets are primarily used for the treatment of:

- **Menopausal Symptoms: Relief from symptoms of estrogen deficiency associated with menopause, such as hot flashes, night sweats, and vaginal dryness.**
- **Hypoestrogenism: Treatment of low estrogen levels in conditions such as premature menopause, primary ovarian insufficiency, or after surgical removal of the ovaries (oophorectomy).**
- **Postmenopausal Osteoporosis Prevention: To prevent osteoporosis in postmenopausal women at high risk of fractures, when alternative treatments are not suitable.**
- **Hormone Replacement Therapy (HRT): To manage symptoms of menopause and improve quality of life in postmenopausal women. It may be used alone or in combination with a progestogen (especially in women with an intact uterus).**
- **Indications for Puberty Induction: In some cases, for hormone therapy in girls with delayed puberty.**

Mechanism of Action:

Estradiol is a potent, naturally occurring estrogen hormone that acts by binding to estrogen receptors in various tissues. It plays a key role in regulating various physiological processes, including:

- Regulation of the menstrual cycle and secondary sexual characteristics in women.
- Bone health by promoting the maintenance of bone density.

- Vaginal and uterine health by supporting mucosal integrity and uterine lining.
- Cardiovascular health by modulating cholesterol levels and arterial function.

Dosage and Administration:

- **Adults (Menopausal Symptoms / Hypoestrogenism):**
 - Typically, 1 tablet (2 mg) daily is prescribed. The dose may be adjusted based on the individual's response and specific medical needs.
 - For optimal results, therapy should be started at the lowest effective dose, and the need for continued treatment should be evaluated periodically.
- **Postmenopausal Osteoporosis Prevention:**
 - The typical starting dose is 1 tablet (2 mg) daily, but this may vary based on clinical evaluation.
- **Puberty Induction (in certain cases):** The dose may vary depending on the individual treatment plan and healthcare provider's instructions.
- The tablet should be taken orally with water, with or without food, as directed by the healthcare provider.

Contraindications:

- Active or past history of breast cancer, endometrial cancer, or any other estrogen-dependent neoplasia.
- Undiagnosed vaginal bleeding or abnormal genital bleeding.
- Active or past history of deep vein thrombosis (DVT), pulmonary embolism, or other thromboembolic disorders.
- Severe liver disease or liver tumors.
- **Pregnancy and breastfeeding:** Not recommended during pregnancy or lactation due to the potential effects on the fetus or infant.
- Hypersensitivity to Estradiol or any of the ingredients in the formulation.

Warnings and Precautions:

- **Cardiovascular Risk:** Long-term use of estradiol may increase the risk of thromboembolic events, such as blood clots, stroke, and heart attack, particularly in women with pre-existing risk factors such as hypertension, diabetes, or smoking.
- **Cancer Risk:** Estrogen therapy has been associated with an increased risk of certain cancers, including endometrial cancer (especially when not used with a progestogen) and breast cancer, particularly with long-term use.
- **Endometrial Health:** Women with an intact uterus should use estradiol in combination with a progestogen to reduce the risk of endometrial hyperplasia and carcinoma.
- **Liver Function:** Caution should be used in patients with liver disorders, as estradiol can impact liver function. Regular liver function tests are recommended during long-term therapy.
- **Hypertension and Hypertriglyceridemia:** Estradiol can increase blood pressure and blood triglycerides, so monitoring is advised for those with pre-existing hypertension or lipid disorders.
- **Glucose Tolerance:** Estradiol can affect glucose metabolism and should be used cautiously in patients with diabetes or insulin resistance.
- **Monitoring:** Regular monitoring of blood pressure, cholesterol, liver function, and bone mineral density is recommended during long-term use.

Side Effects:

Common side effects:

- Headache
- Nausea
- Breast tenderness or enlargement
- Mood changes or depression
- Fluid retention or bloating
- Weight gain or changes in appetite

Serious but rare side effects:

- Thromboembolic events (deep vein thrombosis, pulmonary embolism, stroke)
- Breast cancer or endometrial cancer
- Severe liver dysfunction or jaundice
- Severe allergic reactions (rash, itching, swelling)
- Hypertension (high blood pressure)
- Gallbladder disease

Drug Interactions:

- **CYP450 Enzyme Inducers (e.g., rifampin, phenytoin):** May reduce the effectiveness of estradiol.
- **CYP450 Inhibitors (e.g., ketoconazole, grapefruit juice):** May increase estradiol levels, leading to potential side effects.
- **Anticoagulants (e.g., warfarin):** Estradiol can alter the effects of blood thinners, requiring regular monitoring of clotting parameters.
- **Other Hormonal Medications:** Caution should be exercised when using estradiol with other hormone therapies or birth control pills.

Storage:

- Store at room temperature (below 30°C) in a dry place, away from light and moisture.
- Keep out of reach of children.

Packaging:

- Available in blister packs of 10, 14, or 28 tablets.

Manufacturer:

- [Manufacturer Name]

Note:

Estradiol should be used according to the prescribed dosage and under the supervision of a healthcare provider. It is important to regularly review the benefits and risks of long-term hormone therapy, particularly in postmenopausal women. If you experience any unusual symptoms or side effects, consult your healthcare provider immediately.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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