

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 11/2022

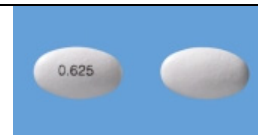
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:PREMARIN TABLETS 0.625mg

Active ingredient:Conjugated estrogens

Dosage form:white tablet, major axis: 11.5 mm, minor axis: 6.7 mm, thickness: 4.0 mm

Imprint or print on wrapping:プレマリン 0.625mg, 0.625, PREMARIN 0.625mg



Effects of this medicine

This medicine replaces female hormone, estrogen, to improve estrogen-dependent gynecologic disorders.

It is usually used to treat ovarian deficiency symptoms, ovarian dysfunction, menopause disorder, vaginitis (senile, childhood and nonspecific) and functional uterine bleeding.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: breast cancer or endometrial cancer, etc. (including history or doubt), thrombophlebitis or pulmonary embolism (including history), coronary heart disease or stroke, etc. (including history), liver disorder, unexplained genital bleeding, untreated endometrial hyperplasia, endometriosis, uterus myoma, heart disease/renal disorder (including history), epilepsy, diabetes mellitus, scheduled surgery within 4 weeks or long-term bedridden state, systemic lupus erythematosus or migraine.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

• Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))

• Ovarian deficiency symptoms, ovarian dysfunction, menopause disorder: In general, for adults, take 1 to 2 tablets (0.625 to 1.25 mg of the active ingredient) a day.

Functional uterine bleeding, vaginitis: In general, take 1 to 6 tablets (0.625 to 3.75 mg of the active ingredient) a day.

In any case, the dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Some foreign studies report that long-term concomitant use of estrogen and progesterone is linked with an increased risk of breast cancer, endometrial cancer, coronary heart disease, stroke or dementia. If you take this medicine, receive an explanation from your doctor to fully understand the necessity and precautions for the concomitant use with progesterone.
- Breast and gynecological examinations (including cytology of the endometrium and ultrasound-guided measurement of the endometrial thickness in patients with uterus) should be performed periodically, if you take this medicine for a long period.
- Stop taking this medicine and contact your doctor or other health-care professionals immediately if some of the following symptoms or conditions occur simultaneously while taking this medicine.
 - Initial symptoms of thrombosis (leg pain/edema, sudden breathing difficulty/shortness of breath, chest pain, dizziness, decreased consciousness, unconsciousness, immobility of limbs, difficulty in seeing letters and figures, visual field abnormality)
 - Conditions increasing the risk of thrombosis (inability to move the body or clearly increased blood pressure, etc.)

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, hives and angioedema. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor

immediately.

- leg pain/edema, a sudden onset of respiratory distress, a sudden onset of declining vision [thrombosis, thromboembolism]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.