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Estratest F.S.

Estratest (Oral)

Generic name: esterified estrogens and methyltestosterone [es-TER-i-fide-ES-troe-jenz, meth-il-tes-TOS-ter-one]

Brand names: Covaryx, Covaryx HS, Essian, Estratest, Menogen, Syntest D.S., Syntest H.S.

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Oral route(Tablet)

Estrogens increase the risk of endometrial cancer; monitor for abnormal vaginal bleeding. Estrogens with or without progestins should not be used for the prevention of cardiovascular disease or dementia. Increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years) have been reported. An increased risk of developing probable dementia in postmenopausal women 65 years or older has also been reported. This product contains an estrogen and androgen, not a progestin. This combination should not be used during a known or suspected pregnancy.

Uses for Estratest

Esterified estrogens and methyltestosterone combination is used to treat the symptoms of menopause in patients who did not get relief after being treated with estrogens alone. These symptoms may include a feeling of heat, sweating, and warmth in the face, neck, or chest ("hot flashes"); and dryness, burning, and itching in the vagina.

Esterified estrogens are a man-made mixture of estrogens. Estrogen is a hormone that is produced by the body in greater amounts in females. It is necessary for normal sexual development of the female and for regulation of the menstrual cycle during the childbearing years. Methyltestosterone is a man-made form of testosterone, a hormone that is produced by the body in greater amounts in males and small amounts in females. Menopause symptoms occur when the hormone balance changes in the female body. This combination of hormones will relieve the symptoms of menopause by adding more hormones to the body.

This medicine is available only with your doctor's prescription.

Before using Estratest

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell

your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

The use of esterified estrogens and methyltestosterone combination is not recommended in children.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of esterified estrogens and methyltestosterone combination in the elderly. However, elderly patients are more likely to develop dementia and age-related kidney, liver, or heart problems, which may require caution and an adjustment in the dose for patients receiving this medicine.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Amifampridine
- Anisindione
- Bupropion
- Dicumarol
- Donepezil
- Phenprocoumon
- · Somatrogon-ghla

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Ginseng
- Levothyroxine
- Licorice
- Tipranavir

Warfarin

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- · Abnormal vaginal bleeding, undiagnosed or
- Blood clotting problems (e.g., deep vein thrombosis, pulmonary embolism), history of or
- · Breast cancer, or history of or
- · Heart attack, recent or history of or
- · Liver disease, severe or
- Stroke, recent or history of—Should not be used in patients with these conditions.
- · Asthma or
- Cancer (e.g., breast, cervix, liver, vagina) or
- Depression, history of or
- Diabetes or
- · Edema (fluid retention) or
- Endometriosis (problem with the lining of the uterus) or
- Epilepsy or
- Eye or vision problems (e.g., retinal vascular thrombosis) or
- · Gallbladder disease or
- · Hepatitis (including cholestatic jaundice), history of or
- Hypercalcemia (high calcium in the blood) or
- Hypocalcemia (high calcium in the blood) or
- Hypothyroidism (underactive thyroid) or
- · Migraine headaches, history of or
- Porphyria (enzyme problem) or
- Systemic lupus erythematosus—Use with caution. May make these conditions worse.
- · Heart or blood vessel disease or
- Hypercholesterolemia (high cholesterol in the blood) or
- Hypertension (high blood pressure) or

- Hypertriglyceridemia (high triglycerides or fat in the blood) or
- Venous thromboembolism (clot in the veins), history of—May increase risk for more serious side effects.

Proper use of Estratest

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

This medicine comes with a patient information insert. Read and follow the instructions in the insert carefully. Ask your doctor if you have any questions.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (tablets):
 - For treatment of menopause symptoms:
 - Adults—One to two tablets once a day.
 - Children—Use is not recommended.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

1 Detailed Estratest F.S. dosage information

Precautions while using Estratest

It is very important that your doctor check your progress at regular visits to make sure the medicine is working properly and to decide if you should continue to take it. These visits should be every 6 to 12 months or as otherwise directed by your doctor.

It is unlikely that a postmenopausal woman may become pregnant. But, you should know that using this medicine while you are pregnant could harm your unborn baby. If you think you have become pregnant while using the medicine, tell your doctor right away.

Very rarely, this medicine can cause serious side effects such as a heart attack or stroke. You are much more likely to have these side effects if you smoke cigarettes or are overweight, or if you have diabetes, high blood pressure, or a high blood cholesterol. Talk with your doctor if you think you might be at risk.

Using large doses of estrogen alone over a long period of time may increase the risk of some kinds of cancer (e.g., endometrial cancer). Talk with your doctor about this risk. If you have vaginal bleeding with this medicine, call your doctor right away.

This medicine may increase the risk of getting breast cancer. It is very important that you check your breasts on a regular basis for any unusual lumps or discharge, and that you have breast x-rays every year as directed by your doctor. These exams are very important if you have a family member with a history of breast cancer. Talk with your doctor about this risk.

This medicine may increase the risk of getting dementia in elderly women (above 65 years of age). Talk with your doctor if this concerns you.

Check with your doctor right away if blurred vision, difficulty with reading, or any other change in vision occurs during or after treatment. Your doctor may want you to have your eyes checked by an ophthalmologist (eye doctor).

Using large doses of methyltestosterone over a long period of time may increase the risk of serious liver problems (e.g., peliosis hepatis or liver cancer). Talk with your doctor about this risk.

Before you have any medical tests, tell the medical doctor in charge that you are taking this medicine. The results of some tests may be affected by this medicine. Also, you may need to stop using this medicine for a few weeks before and after having surgery, or if you are inactive for a long period of time.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects of Estratest

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- · Absent, missed, or irregular menstrual periods
- · acne or oily skin
- · decreased breast size
- · enlarging clitoris
- hoarseness or deepening of the voice
- · menstrual changes

- · stopping of menstrual bleeding
- · unnatural hair growth or loss

Rare

- · Continuing nausea
- cough
- · dark-colored urine
- · difficulty with swallowing
- dizziness
- · fast heartbeat
- fever
- hives
- itching
- · light-colored stools
- · loss of appetite
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- purple or red-colored spots on the body or inside the mouth or nose
- · shortness of breath
- skin rash
- sore throat
- tightness in the chest
- · unusual tiredness or weakness
- vomiting
- wheezing

Incidence not known

- Abdominal or stomach bloating, cramps, or pain
- anxiety
- · bleeding from gums or nose
- blistering, peeling, or loosening of the skin
- bloating
- bloody or cloudy urine
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- · change in vaginal discharge
- · changes in skin color, pain, or tenderness

- chest pain or discomfort
 chills
 clay-colored stools
- clear or bloody discharge from nipple
- confusion
- constipation
- convulsions
- · darkening of urine
- · decrease in amount of urine
- diarrhea
- difficult, burning, or painful urination
- · difficulty with breathing
- · difficulty with moving
- · difficulty with speaking
- dimpling of the breast skin
- · dizziness or lightheadedness
- double vision
- eye pain
- fainting
- fever
- fluid-filled skin blisters
- frequent urge to urinate
- headache
- heavy bleeding
- inability to move the arms, legs, or facial muscles
- · inability to speak
- indigestion
- inverted nipple
- · irregular heartbeats
- itching of the vagina or genital area
- joint or muscle pain
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- · light-colored stools
- · loss of appetite

- lump in the breast or under the arm
- · mood or mental changes
- · muscle cramps in the hands, arms, feet, legs, or face
- · muscle pain or stiffness
- nausea
- · noisy, rattling breathing
- numbness and tingling around the mouth, fingertips, or feet
- pain
- · pain during sexual intercourse
- pain in the ankles or knees
- pain or discomfort in the arms, jaw, back, or neck
- · pain or feeling of pressure in pelvis
- · painful, red lumps under the skin, mostly on the legs
- pains in the stomach, side, or abdomen, possibly radiating to the back
- · pelvic pain
- persistent crusting or scaling of the nipple
- pinpoint red or purple spots on the skin
- poor insight and judgment problems with memory or speech
- red, irritated eyes
- · redness or swelling of the breast
- · ringing in the ears
- · sensitivity to the sun
- shortness of breath
- skin thinness
- slow speech
- · sore on the skin of the breast that does not heal
- sore throat
- · sores, ulcers, or white spots in the mouth or on the lips
- · stomach pain
- sudden shortness of breath or troubled breathing
- sweating
- swelling
- swelling of the fingers, hands, feet, or lower legs

- · tenderness of the breast
- · thick, white curd-like vaginal discharge without odor or with mild odor
- tiredness
- tremor
- · trouble recognizing objects
- · trouble thinking and planning
- · trouble walking
- · troubled breathing at rest
- unexpected or excess milk flow from breasts
- · unpleasant breath odor
- · vaginal bleeding
- · vision changes
- · vomiting of blood
- weakness
- · weight gain
- yellow eyes or skin

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

Incidence not known

- Blemishes on the skin
- brown, blotchy spots on the exposed skin
- decreased interest in sexual intercourse
- depression
- · headache, severe and throbbing
- inability to have or keep an erection
- increase or decrease in weight
- increased hair growth, especially on the face
- increased in sexual ability, desire, drive, or performance
- · increased interest in sexual intercourse
- irritability
- · leg cramps
- loss in sexual ability, desire, drive, or performance

- · loss of hair
- · mental depression
- pimples
- · redness of the skin
- · swelling or inflammation of the mouth
- twitching, uncontrolled movements of the tongue, lips, face, arms, or legs

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Estratest F.S. side effects (more detail)

Commonly used brand name(s)

In the U.S.

- Covaryx
- Covaryx HS
- Essian
- Estratest
- Menogen
- Syntest D.S.
- · Syntest H.S.

Available Dosage Forms:

Tablet

Therapeutic Class: Estrogen/Androgen Combination

Pharmacologic Class: Estrogen

More about Estratest F.S. (esterified estrogens / methyltestosterone)

- · Check interactions
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- Dosage information
- During pregnancy

Patient resources

Other brands

EEMT, Essian, Covaryx, EEMT HS, ... +4 more

Professional resources

- Estratest prescribing information
- Estratest FS (FDA)

Other brands

EEMT, Covaryx, Syntest DS, Syntest HS

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

3 Moderate abuse potential

WADA Class

്റ്റ് Anti-Doping Classification

User Reviews & Ratings

3 Reviews

Images

Estratest F.S. 1.25 mg / 2.5 mg (SOLVAY 1026)



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