

Consumer Medication Information Leaflet (RiMUP)

FEMOSTON[®] 1/10 TABLET

Estradiol (1mg), dydrogesterone (10mg)

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What Femoston[®] is used for

Femoston[®] is used in postmenopausal women who still have a uterus (womb) as hormone replacement therapy.

This product is not recommended for women older than 65 years.

How Femoston[®] works

Femoston[®] acts as a hormone replacement therapy by providing two types of female hormones, an oestrogen called estradiol and a progestogen called dydrogesterone.

Before you use Femoston[®]

- When you must not use it

Do not take Femoston[®]:

- If you have or have ever had breast cancer, or if you are suspected of having it
- if you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it.
- if you have or your doctor thinks you might have a tumor that is dependent on progestogens. An example is a tumor in the brain (meningioma).

- if you have any unexplained vaginal bleeding
- if you have excessive thickening of the womb lining that is not being treated
- if you have or have ever had a blood clot in a vein such as in the legs or the lungs
- if you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency)
- if you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, or angina
- you have or have ever had a liver disease and your liver function tests have not returned to normal
- if you have porphyria (a metabolic disorder)
- if you are allergic (hypersensitive) to estradiol, dydrogesterone or to any of the other ingredients of Femoston[®].
- increased risk of developing blood clots
- increased risk of getting an oestrogen-sensitive cancer (such as family history)
- high blood pressure
- diabetes
- gallstones
- migraine or severe headaches
- systemic lupus erythematosus (a type of immune disorder)
- epilepsy
- asthma
- abnormal growth of bone in the ear (otosclerosis)
- a very high level of fat in your blood (triglycerides)
- heart or kidney problems

If you are not sure, talk to your doctor or pharmacist before taking Femoston[®].

- Before you start to use it

Talk to your doctor or pharmacist before taking Femoston[®] if you suffer from any medical conditions or illness and/or have been aggravated during pregnancy or previous hormone treatment especially:

- growth of womb lining outside your womb (endometriosis) or noncancerous growth of the womb

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for epilepsy (such as phenobarbital, carbamazepine, phenytoin)
- medicines for tuberculosis (such as rifampicin, rifabutin)
- medicines for HIV infection [AIDS] (such as nevirapine, efavirenz, ritonavir, nelfinavir)
- herbal remedies containing St John's wort (*Hypericum perforatum*).

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- medicine for immunosuppressant (such as tacrolimus, cyclosporine A)
- medicine for painkiller (such as fentanyl)
- medication for asthma (such as theophylline)

How to use Femoston®

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

If you are still menstruating, begin treatment on the first day of menstruation.

If you are menstruating infrequently, begin treatment after 10-14 days of progestogen therapy.

If you had your last period more than approximately 12 months ago, start treatment at any time.

Take one white tablet every day for the first 14 days followed by one grey tablet every day for the next 14 days. This is shown on the 28 days calendar pack.

- When to use it

Use as directed by your doctor or pharmacist.

Femoston® may be taken with or without food. Try to take your tablet at the same time each day. This will make sure that there is a constant amount of the product in your body. This will also help you remember to take your tablets.

Take one tablet every day, without a break between packs. The blisters are marked with the days of the week.

This makes it easier for you to remember when to take your tablets.

- How long to use it

Continue taking Femoston® for as long as your doctor or pharmacist recommends.

- If you forget to use it

If you forgotten a dose, take it as soon as possible. If you are more than 12 hours late in taking the dose, take the next dose at your regular time on the next day. Do not take a double dose to make up for the forgotten dose. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you take more Femoston® than you should stop taking Femoston® and talk to a doctor or pharmacist.

Symptoms of overdose include nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue, and withdrawal bleeding.

While you are using it

- Things you must do

Stop the therapy and tell your doctor immediately if you become pregnant while taking this medication

- Things to be careful of

Stop the therapy if you have significant increase in blood pressure.

If you experience any symptoms of blood clot, such as painful swelling in leg, shortness of breath or sudden pain in chest, please contact your doctor immediately.

Breakthrough bleeding and spotting may occur during the first month of

treatment. If breakthrough bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, please consult your doctor or pharmacist.

Pregnancy and breast feeding

Femoston® is for use in postmenopausal women only.

Important information about some of the ingredients of Femoston®

Femoston® contain lactose sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Driving and Use of Machines

Femoston® has no or negligible influence on the ability to drive and use machines

Side effects

Like all medicines, Femoston® can cause side effects, although not everybody gets them.

The following diseases are reported more often in women using HRT compared to women not using HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb
- ovarian cancer
- blood clots in the veins of the legs or lungs
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

Very common (may affect more than 1 in 10 people):

- headache

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- abdominal pain
- back pain
- tender or painful breasts

Common (may affect up to 1 in 10 people):

- vaginal fungal infection
- feeling depressed, nervousness
- migraine. If you have a migraine-like headache for the first time, stop taking Femoston[®] and see a doctor immediately
- dizziness feeling sick, vomiting, wind (flatulence)
- allergic skin reactions (such as rash, severe itching or hives)
- menstrual disorders such as irregular bleeds or spotting, painful periods, heavier or no bleeding
- vaginal fluid discharge
- feeling weak, tired or unwell
- swelling of your ankles, feet or fingers
- weight increase

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Femoston[®]

- Storage

Keep this medicine out of the sight and reach of children. Do not use Femoston[®] after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Femoston[®] tablets are round, biconvex and have 379 marked on one side. Each blister strip contains 28 tablets.

Femoston[®] 1/10 Tablets contains two different coloured tablets. Each blister strip contains 14 white tablets (for the first 14 days of the cycle) and 14 grey tablets (for the second 14 days of the cycle).

Femoston[®] is available in cartons of 28's, 84's and 280's. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

White tablet contains 1mg of estradiol hemihydrate, while grey tablet contains 1mg of estradiol hemihydrate and 10mg of dydrogesterone.

- Inactive ingredients

Lactose monohydrate, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate.

White tablet: Film coating mix

White I (titanium dioxide (E171), hypromellose, macrogol 400)

Grey tablet: Film coating mix

Grey I

85F27664 (titanium dioxide (E171), iron oxide black (E172), polyvinyl alcohol, macrogol 3350, talc)

- MAL number:

Femoston[®] 1/10 Tablet:
MAL20040819AZ

Manufacturer

Abbott Biologicals B.V.,
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Product Registration Holder

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