Package Leaflet: Information for the user

Femoston 2/10mg film-coated tablets

estradiol / dydrogesterone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor, pharmacist or nurse.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Femoston is and what it is used for

Femoston is a Hormone Replacement Therapy (HRT). It contains two types of female hormones:
• An estrogen called estradiol
• A progestogen called dydrogesterone.
Femoston is used in postmenopausal women with at least 6 months since their last natural period.

Femoston is used for:
• **Relief of symptoms occurring after menopause.**
During the menopause, the amount of the estrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). Femoston alleviates these symptoms after menopause. You will only be prescribed Femoston if your symptoms seriously hinder your daily life.
• **Prevention of osteoporosis**
After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor. If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use Femoston to prevent osteoporosis after menopause.

2. What you need to know before you take Femoston

Medical history and regular check-ups
The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.
The experience in treating women with a premature menopause (due to ovarian failure or surgery) is limited. If you have a premature menopause the risks of using HRT may be different. Please talk to your doctor.
Before you start (or restart) HRT, your doctor should ask about your own and your family's medical history. Your doctor may decide to perform a physical examination.This may include an examination of your breasts and/or an internal examination, if necessary. Screening tests including appropriate imaging tools, e.g. mammography (an X-ray of the breasts), should be performed according to current medical recommendations. Your doctor will tell you how often these tests should be performed. They will only do this if it is necessary for you or if you have any special concerns.
Once you have started on Femoston, you should see your doctor for regular check-ups (at least once a year).
At these check-ups, your doctor may discuss with you the benefits and risks of continuing to take Femoston.

DO NOT take Femoston
if any of the following applies to you. If you are not sure about any of the points below, **talk to your doctor** before taking Femoston.
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 estrogens** such as cancer of the womb lining (endometrium), or if you are suspected of having it
• if you have any **unexplained vaginal bleeding**
• if you have **excessive thickening of the womb lining** (endometrial hyperplasia) that is not being treated
• if you have or have ever had a **blood clot in a vein** (thrombosis), such as in your legs (a deep vein thrombosis), or your lungs (a pulmonary embolism)
• 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 **angina, heart attack, or stroke**
• if you have or have ever had a **liver disease** and your liver function tests have not returned to normal
• if you have a rare blood problem called "porphyria" which is passed down in families (inherited)
• if you are **allergic** (hypersensitive) to estradiol, dydrogesterone or any of the other ingredients of Femoston (listed in Section 6)
• if you have meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull).

If any of the above conditions appear for the first time while taking Femoston, stop taking it at once and consult your doctor immediately.

Warnings and Precautions
When to take special care with Femoston
Tell your doctor if you have ever had any of the following problems, before you start the treatment, as these may return or become worse during treatment with Femoston. If so, you should see your doctor more often for check-ups:
• fibroids inside your womb

• growth of the womb lining outside the womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
• increased risk of developing blood clots (see "Blood clots in a vein (thrombosis)")
• increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
• high blood pressure
• a liver disorder, such as a benign liver tumour
• diabetes
• gallstones
• migraine or severe headache
• a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
• epilepsy
• asthma
• a disease affecting the eardrum and hearing (otosclerosis)
• a very high level of fat in your blood (triglycerides)
• fluid retention due to cardiac or kidney problems
• hereditary and acquired angioedema

Stop taking Femoston and see a doctor immediately

If you notice any of the following when taking HRT:
- any of the conditions mentioned in the 'DO NOT take Femoston' section
- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- swollen face, tongue and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of an angioedema
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
  painful swelling and redness of the legs
  sudden chest pain
  difficulty in breathing
  For more information, see 'Blood clots in a vein (thrombosis)'

Note: Femoston is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy. Speak to your doctor for advice.

<u>HRT and Cancer</u>

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Taking estrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer). The progestogen in Femoston protects you from this extra risk.

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking Femoston. But, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:
• carries on for more than the first 6 months
• starts after you have been taking Femoston for more than 6 months
• carries on even after you have stopped taking Femoston

see your doctor as soon as possible.

Breast cancer

Evidence shows that taking combined estrogen-progestogen or estrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Compare

Women aged 50 to 54 who are not taking HRT, on average, 13 to 17 in 1000 will be diagnosed with breast cancer over a 5-year period. For women aged 50 who start taking estrogen-only HRT for 5 years, there will be 16-17 cases in 1000 users (i.e. an extra 0 to 3 cases). For women aged 50 who start taking estrogen-progestogen HRT for 5 years, there will be 21 cases in 1000 users (i.e. an extra 4 to 8 cases).

Women aged 50 to 59 who are not taking HRT, on average, 27 in 1000 will be diagnosed with breast cancer over a 10-year period. For women aged 50 who start taking estrogen-only HRT for 10 years, there will be 34 cases in 1000 users (i.e. an extra 7 cases). For women aged 50 who start taking estrogen-progestogen HRT for 10 years, there will be 48 cases in 1000 users (i.e. an extra 21 cases).

Regularly check your breasts. See your doctor if you notice any changes, such as:
• dimpling of the skin
• changes in the nipple
• any lumps you can see or feel

Additionally, you are advised to join mammography screening programs when offered to you. For mammogram screening, it is important that you inform the nurse/healthcare professional who is actually taking the x-ray that you use HRT, as this medication may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

Ovarian cancer is rare – much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

The risk of ovarian cancer varies with age. For example, in women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period. For women who have been taking HRT for 5 years, there will be about 3 cases per 2000 users (i.e. about 1 extra case).

<u>Effect of HRT on heart and circulation</u>

Blood clots in a vein (thrombosis)

The risk of **blood clots in the veins** is about 1.3 to 3- times higher in HRT users than in non-users, especially during the first year of taking it.
Blood clots can be serious and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.
You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you.
Inform your doctor if any of these situations applies to you:
• you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, If you need to have surgery).
• you are seriously overweight (BMI >30 kg/m^2)
• you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
• any of your close relatives has ever had a blood clot in the leg, lung or another organ
• you have systemic lupus erythematosus (SLE).
• you have cancer
For signs of a blood clot, see "Stop taking Femoston and see a doctor immediately"
Compare
Looking at women in their 50s who are not taking HRT, on average, over a 5-year period, 4 to 7 in 1000 would be expected to get a blood clot in a vein.
For women in their 50s who have been taking estrogen-progestogen HRT for over 5 years, there will be 9 to 12 cases in 1000 users (i.e. an extra 5 cases).

Heart disease (heart attack)
There is no evidence that HRT will prevent a heart attack.
Women over the age of 60 years who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke
The risk of getting stroke is about 1.5 times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT will increase with age.
Compare
Looking at women in their 50s who are not taking HRT, on average, 8 in 1000 would be expected to have a stroke over a 5-year period. For women in their 50s who are taking HRT, there will be 11 cases in 1000 users, over 5 years (i.e. an extra 3 cases).

Meningioma
Use of Femoston has been linked to the development of a generally benign tumour of the tissue layer between the brain and the skull (meningioma). If you are diagnosed with meningioma, your doctor will stop your treatment with Femoston (see section "Do not take…"). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

Other conditions
HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Tell your doctor if you have or have had any of the following medical conditions since he will have to monitor you more closely:
- **heart disease**
- **kidney impairment**
- **higher than normal levels of certain blood fats (hypertriglyceridemia)**

Children
Femoston is intended only for postmenopausal women.

Other medicines and Femoston
Some medicines may interfere with the effect of Femoston. This might lead to irregular bleeding. This applies to the following medicines:
The following medicines may **lower the effect of Femoston** and lead to bleeding or spotting:
• medicines for **epilepsy** (such as phenobarbital, phenytoin, carbamazepine)
• medicines for **tuberculosis** (such as rifampicin, rifabutin)
• medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir, nelfinavir)
• herbal remedies containing **St John's Wort** (Hypericum perforatum).

HRT can affect the way some other medicines work:
• A medicine for epilepsy (lamotrigine), as this could increase frequency of seizures
• medicines for Hepatitis C virus (HCV) such as combination regimens ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin; glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir may cause increases in liver function blood test results (increase in ALT liver enzyme) in women using CHCs containing ethinylestradiol. Femoston contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when using Femoston with this HCV combination regimen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription, herbal medicines or other natural products. Your doctor will advise you.

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking Femoston, because this medicine can affect the results of some tests.

Femoston with food and drink
Femoston can be taken with or without food.

Pregnancy and breast-feeding
Femoston is for use in postmenopausal women only. If you become pregnant, stop taking Femoston and contact your doctor.

Femoston is not indicated for use during breast-feeding.

Driving and using machines
The effect of Femoston on driving and using machinery has not been studied. An effect is unlikely.

Femoston tablets contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Femoston

Always take Femoston exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When to start taking Femoston
Do not start taking Femoston until at least 6 months after your last natural period.
You can start taking Femoston on any convenient day if:
• you are currently not taking any HRT product
• you are switching from a "continuous combined" HRT product. This is where you take a tablet or use a patch every day that contains both an estrogen and a progestogen.
You start taking Femoston the day after you finish the 28 day cycle if:
• you are switching from a "cyclic" or "sequential" HRT product. This is where you take a tablet or use a patch that contains estrogen for the first part of your cycle. Afterwards you take a tablet or use a patch containing both an estrogen and a progestogen for up to 14 days.

Taking this medicine
Take one tablet every day, without a break between packs. The blisters are marked with the days of the week to make it easier for you to remember when to take your tablets. Start by taking the tablets from the part marked with arrow 1. Then take the tablets from the part marked with arrow 2.
• Swallow the tablet with water.
• You can take your tablet 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 medicine in your body. This will also help you remember to take your tablets.

How much to take
Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary. Speak to your doctor if you think this dose is too strong or not strong enough.
If you are taking Femoston to prevent osteoporosis, your doctor will adjust the dose to suit you. It will depend on your bone mass. Take one brick red tablet every day for the first 14 days. One yellow tablet is then taken every day for the next 14 days. This is shown on the 28 day calendar pack.

If you need to have surgery
If you are going to have a surgery, tell the surgeon that you are taking Femoston. You may need to stop taking Femoston about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see Section 2, Blood clots in a vein). Ask your doctor when you can start taking Femoston again.

If you take more Femoston than you should
If you (or someone else) take too many Femoston tablets, you are unlikely to come to any harm. You may feel sick (nauseous), or be sick (vomit), may have tender breasts, dizziness, abdominal pain, drowsiness/tiredness, or withdrawal bleeding. No treatment is necessary. But if you are worried, contact your doctor for advice.

If you forget to take Femoston
Take the missed tablet as soon as you remember. If it is more than 12 hours after you should have taken the tablet, take the next dose at the regular time. Do not take the forgotten tablet. Do not take a double dose. Bleeding or spotting may occur if you miss a dose.

If you stop taking Femoston
Do not stop taking Femoston without first talking to your doctor.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Stop taking Femoston and see a doctor straight away or go to hospital, if you notice or suspect any of the following. You may need urgent medical treatment:
• swollen face, lips or tongue often with breathing problems (angioedema)
• if you get painful swelling in your leg, sudden chest pain or have difficulty breathing. These could be signs of a blood clot
• an unexpected headache, which could be a sign of high blood pressure
• sudden problems with your vision or an unexpected migraine
• breast cancer (you may notice dimpling of the skin, changes in the nipple or lumps that you can see or feel)
• abnormal or unexpected vaginal bleeding (for more details on what bleeding might be expected please read "Endometrial cancer" in "Safety of HRT"). These could be signs of a thickening of the lining of the womb (endometrial hyperplasia)
• angina, heart attack or stroke
• persistent pelvic and abdominal pain and bloating, difficulty eating, feeling full quickly which could be signs of ovarian cancer
• yellowing of the skin or eyes (jaundice) or other liver changes
• you become pregnant.
If you notice or suspect any of the above, stop taking Femoston and see a doctor straight away or go to hospital.

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 (endometrial hyperplasia or cancer)
- ovarian cancer
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- probable memory loss if HRT is started over the age of 65

For more information about these side effects, see Section 2.

The following side effects may happen with this medicine:

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

• headache
• abdominal pain
• back pain
• tender or painful breasts

Common (may affect up to 1 in 10 patients)

• vaginal thrush (a vaginal infection due to a fungus called Candida albicans)
• 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 (nausea), vomiting, bloating (swelling of the abdomen) including wind (flatulence)
• allergic skin reactions (such as rash, severe itching (pruritus) or hives (urticaria))
• menstrual disorders such as irregular bleeds, spotting, painful periods (dysmenorrhoea), heavier or less bleeding
• pelvic pain
• vaginal discharge
• feeling weak, tired or unwell
• swelling of you ankles, feet or fingers (peripheral oedema)
• weight increase

Uncommon (may affect up to 1 in 100 patients)

• cystitis-like symptoms
• growths in the womb (fibroids) get bigger
• hypersensitivity reactions such as dyspnoea (allergic asthma)
• change in your sex drive
• blood clots in the legs or lungs (*deep vein thrombosis or pulmonary embolism*)
• high blood pressure (hypertension)
• problems with your circulation (peripheral vascular disease)
• enlarged and tortuous (varicose) vein
• indigestion
• liver disorders, sometimes with yellowing of the skin (jaundice), feeling weak (asthenia) or generally feeling unwell (malaise), and abdominal pain. If you notice yellowing of the skin or the whites of your eyes, stop taking Femoston and see a doctor immediately
• gall-bladder disease
• swelling of your breasts
• pre-menstrual syndrome (PMS)
• weight decrease

Rare (may affect up to 1 in 1,000 patients)

(*Side effects from the market not observed in clinical trials have been attributed to the frequency “rare”)
• illness resulting from the destruction of red blood cells (haemolytic anaemia)*
• meningioma (a brain tumour)*
• change in the surface of the eye (steepening of corneal curvature)*, not being able to wear your contact lenses (contact lenses intolerance)*
• heart attack (*myocardial infarction*)
• stroke*
• swelling of the skin around the face and the throat. This may cause difficulty in breathing (angioedema)
• purplish patches or spots on the skin (vascular purpura)
• painful reddish skin nodules (erythema nodosum)*, discolouration of the skin especially of the face or neck known as “pregnancy patches” (chloasma or melasma)*
• leg cramps*

The following side effects have been reported with HRTs:

• benign or malignant tumours which may be affected by the levels of estrogens such as cancer of the womb lining, ovarian cancer (see section 2 for more information)
• increased size of tumours that may be affected by the levels of progestogens (such as meningioma)
• a disease where the immune system abnormally attacks many organs of the body (systemic lupus erythematosus)
• probable dementia
• worsening of fits (epilepsy)
• muscle twitches you cannot control (chorea)
• blood clots in the arteries (arterial thromboembolism)
• inflammation of the pancreas (pancreatitis) in women with pre-existing high levels of certain blood fats (hypertriglyceridemia)
• rash with target-shaped reddening or sores (erythema multiforme)
• urinary incontinence
• painful/lumpy breasts (fibrocystic breast disease)
• erosion of the neck of the womb (uterine cervical erosion)
• worsening of a rare blood pigment disorder (porphyria)
• high levels of certain blood fats (hypertriglyceridemia)
• increased total thyroid hormones

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (details below). By reporting side effects you can help provide more information on the safety of this medicine.
In Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie.
In Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Femoston
This medicinal product does not require any special storage conditions.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the outer carton and blister strip after EXP.
The expiry date refers to the last day of that month.
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.

6. Contents of the pack and other information
What Femoston contains
The active substances are estradiol (as hemihydrate) and dydrogesterone. Each pack of Femoston contains two different types of tablets.
• Each brick red tablet contains 2mg of estradiol (as hemihydrate).
• Each yellow tablet contains 2mg estradiol (as hemihydrate) and 10mg dydrogesterone.
In both tablet cores, the other ingredients are lactose monohydrate, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate.
The other ingredients in the coating of the brick red tablets are hypromellose, macrogol 400, titanium dioxide (E171) and iron oxides, red, black, yellow (E172), talc.
The other ingredients used in the coating of the yellow tablets are hypromellose, macrogol 400, titanium dioxide (E171) and iron oxides yellow (E172), talc.

What Femoston looks like and contents of the pack
The tablets are brick red (containing estradiol (as hemihydrate)) and yellow (containing estradiol (as hemihydrate), and dydrogesterone). Both tablets have marked ‘379’ on one side
Femoston is available as a one month pack containing one strip of 28 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Theramex Ireland Limited, 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin, Ireland, DO1 YE64.
Manufacturer:
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This leaflet was revised in November 2025.