PACKAGE LEAFLET:
INFORMATION FOR THE USER
Femoston® 1/10mg and Femoston® 2/10 mg

Active substances: oestradiol hemihydrate and 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, or 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 oestrogen and a progestogen. HRT is used in woman who require oestrogen replacement and who have not had their womb removed (hysterectomy). Femoston is used in postmenopausal women at least 6 months since last menses.

Femoston is used for:
Relief of symptoms occurring after menopause
During the menopause, the amount of oestrogen 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 will 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. Once you have started on Femoston you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with Femoston. Go for regular breast screening, as recommended by your doctor.

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 oestrogens**, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- If you have a tumor which is sensitive to progestogen, such as a tumor of the brain (meningioma)
- 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 the legs (deep venous thrombosis) or the lungs (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 a **heart attack, stroke or angina**
- 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 **oestradiol/ dydrogesterone** or any of the other ingredients of Femoston (listed in section 6 Further information)

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

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 womb lining outside your 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 oestrogen-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 headaches
- 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.

HRT and cancer

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

Irregular bleeding
You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of taking Femoston. However, if the irregular bleeding:
- carries on for more than the first 6 months
- starts after you have been taking Femoston for more than 6 months
- carries on after you have stopped taking Femoston

see your doctor as soon as possible.

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 more than 6 months
- carries on after you have stopped taking Femoston

see your doctor as soon as possible

Breast cancer
Evidence shows that taking combined oestrogen-progestogen or oestrogen-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 oestrogen-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 oestrogen-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 oestrogen-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 oestrogen-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

Ovarian cancer
Ovarian cancer is rare much rarer than breast cancer. The use of oestrogen-only or combined oestrogen-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).

Effect of HRT on heart and circulation 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/m2)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or any other 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 oestrogen-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 oestrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke
The risk of having a 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).

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.

Using other medicines

Some medicines may interfere with the effect of Femoston. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines for **epilepsy** (such as phenobarbital, phenytoin and carbamazepine)
- Medicines for **tuberculosis** (such as rifampicin and rifabutin)
- Medicines for **HIV infection** (such as nevirapine, efavirenz, ritonavir and nelfinavir)
- Herbal remedies containing **St John's Wort**
- Medicines for Hepatitis C virus (HCV) (such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir) 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. Your doctor will advise you.

Problems due to high levels of the following medicines may occur when you take Femoston so careful drug monitoring and dose decrease may become necessary:

- tacrolimus and cyclosporin – used, for example, for organ transplants
- fentanyl – a painkiller
- theophylline – used for asthma and other breathing problems

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.

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.

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

Femoston tablets contain *lactose*
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

How to take Femoston
Take one tablet every day, without a break between packs. Swallow the tablet with water, with or without food. Your doctor will aim to give you the lowest dose for the shortest time to treat your symptoms. Speak to your doctor if you think this dose is too strong or not strong enough.
The usual starting dose is:
During day 1 to 14 of the cycle, 1 tablet daily containing 1 or 2 mg oestradiol.
During day 15 to 28 of the cycle, 1 tablet daily containing 1 or 2 mg oestradiol and 10 mg dydrogesterone.
Immediately after the 28-day cycle you should begin the next treatment.
The days of the week are printed on the back of the blister strips. The tablets from the part marked with arrow 1 should be taken first, then the tablets from the part marked with arrow 2 should be taken.
If you are not having periods and are not taking any other Hormone Replacement Therapy (HRT) preparations, or you are switching from a combined continuous HRT product, you can start taking Femoston on any convenient day.
If you are currently using a 'cyclic' or 'sequential' HRT preparation (which involves taking an oestrogen tablet or patch for part of the month, followed by both oestrogen and progestogen tablet or patch for up to 14 days) start taking Femoston the day after you finish the pack i.e. at the end of the

progestogen phase. The doctor may increase the dose later, if necessary. The different tablet strengths are colour-coded for your convenience. If you are taking Femoston to treat symptoms of the menopause (change of life), your treatment should begin with the dosage Femoston 1/10. Your doctor will then increase this dose according to your symptoms. If you are taking Femoston to prevent osteoporosis, your doctor will adjust the dose individually according to your bone mass.

If you take more Femoston than you should
If you or somebody else takes too many Femoston tablets, they are unlikely to come to any harm. Nausea (feeling sick), vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue, and withdrawal bleeding may occur. 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 since you took the last one, take the next dose without taking 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 or pharmacist.

If you need to have surgery
If you are going to have 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.

4. POSSIBLE 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 (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 serious side effects may occur during treatment with Femoston:

- allergic reactions that may cause swelling of the skin around the face and neck. This may cause difficulty breathing
- heart attack
- tumours that may be affected by the levels of progestogens (e.g. meningioma)
- heavy, irregular or painful genital bleeding

If any of these side effects occur you should stop treatment immediately and contact your doctor. The following side effects may occur during treatment:

Very common (in more than 1 in 10 patients treated):

- headache
- abdominal pain
- back pain
- breast pain or tenderness

Common (in less than 1 in 10, but more than 1 in 100 patients treated):

- vaginal thrush (a vaginal infection due to a fungus called Candida albicans)
- depression
- nervousness
- migraine
- dizziness
- feeling sick
- vomiting
- wind (flatulence)
- allergic skin reactions (including rash or itching)
- unscheduled bleeding or spotting, heavy, irregular
- or painful periods
- pelvic pain
- vaginal discharge
- generally feeling unwell, weak or tired
- swelling of the ankles, feet or fingers (peripheral oedema)
- increase in weight

Uncommon (in less than 1 in 100, but more than 1 in 1,000 patients treated):
- symptoms of cystitis
- fibroids get bigger (growths in the womb increase)
- change in sex drive
- high blood pressure
- peripheral vascular disease
- varicose veins
- blood clots in the veins of the legs or lungs (venous thromboembolism)
- indigestion
- liver disorders, which may include jaundice (yellowing of the skin), asthenia (feeling weak) and general malaise and abdominal pain
- gall bladder disorder
- swelling of the breasts
- pre-menstrual tension (PMT)
- decrease in weight

Rare (in less than 1 in 1,000, but more than 1 in 10,000 patients treated):
- heart attack
- swelling of the skin around the face and neck. This may cause difficulty breathing
- red or brown patches on the skin

If unscheduled bleeding occurs after some time on HRT, you should contact your doctor. If unscheduled bleeding continues after stopping HRT, it may be necessary to perform tests to exclude disease of the endometrium (the lining of the uterus). Changes can occur in the levels of certain proteins and hormones in the blood. The action of the hormones in the body is not affected. You should tell your doctor that you are taking HRT if you are to have a blood test.
The following side effects have been reported with HRTs (including Femoston):
- benign or malignant tumours which may be affected by the levels of oestrogens, such as cancer of the womb lining, ovarian cancer
- increased size of tumours that may be affected by the levels of progestogens (such as meningioma)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- a disease where the immune system abnormally attacks many organs of the body (systemic lupus erythematosus)
- high levels of certain blood fats (hypertriglyceridemia)
- loss of mental abilities such as thinking, remembering and reasoning (dementia)
- chorea (muscle twitches)
- worsening of fits (epilepsy)

- change in the surface of the eye
- intolerance to contact lenses
- blood clots in the arteries (arterial thromboembolism)
- inflammation of the pancreas (pancreatitis) in women with pre-existing high levels of certain blood fats (hypertriglyceridemia)
- various skin disorders: discoloration of the skin especially of the face or neck known as "pregnancy patches" (chloasma), painful reddish skin nodules (erythema nodosum), rash with target-shaped reddening or sores (erythema multiforme)
- Leg cramps
- urinary incontinence
- painful/lumpy breasts (fibrocystic breast changes), uterine cervical erosion
- worsening of porphyria (a rare blood pigment disorder)
- increased total thyroid hormones

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 systems listed below.The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FEMOSTON

Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions. Do not take Femoston after the "use before" date, which is stated on the pack. The "use before" date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Femoston contains
• The active substances are:
- oestradiol
- dydrogesterone

Femoston 1/10
Contains 14 white tablets with 1 mg oestradiol per tablet for the first 14 days of the cycle and 14 grey tablets with 1 mg oestradiol and 10 mg dydrogesterone for the second 14 days of the cycle.
Femoston 2/10
Contains 14 brick red tablets with 2 mg oestradiol per tablet for the first 14 days of the cycle and 14 yellow tablets with 2 mg oestradiol and 10 mg dydrogesterone for the second 14 days of the cycle.

- The other ingredients in the tablet core are: lactose, hypromellose, maize starch, colloidal anhydrous silica, magnesium stearate
- The other ingredients in the film coating for Femoston 1/10 oestradiol only are: hypromellose, macrogol 400, titanium dioxide (E171)
- The other ingredients in the film coating for Femoston 1/10 oestradiol/dydrogesterone are: Polyvinylalcohol, Macrogel 3350, talc, titanium dioxide (E171), black iron oxide (E172).
- The other ingredients in the film coating for Femoston 2/10 oestradiol only are: hypromellose, talc, macrogol 400, titanium dioxide (E171), black, red, and yellow iron oxides (E172).
- The other ingredients in the film coating for Femoston 2/10 oestradiol/dydrogesterone are: hypromellose, talc, macrogol 400, titanium dioxide (E171), yellow iron oxide (E172).

What Femoston looks like and contents of the pack
Film-coated tablets.
Femoston 1/10 Round white film-coated tablets and round grey film-coated tablets. The inscription on the tablets is ‘379’ on one side. The tablets are packed in a PVC film with a covering aluminium foil. The blister packs contain 84 film-coated tablets.
Femoston 2/10 Round brick red film-coated tablets and round yellow film-coated tablets. The inscription on the tablets is ‘379’ on one side. The tablets are packed in a PVC/PVdC or PVC film with a covering aluminium foil.
The blister packs contain 28 or 84 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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