femoston 1/10 mg
femoston 2/10 mg

Active substances: oestradiol hemihydrate and dupirene.

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.
- This medicine has been prescribed for you only. Do not give it to anyone else. It may help to remind you of the correct dosage and other information in the event that you need to read it again.

If you notice signs of a blood clot, such as:
- changes in the nipple
- Regularly check your breasts. See your doctor if:
- sudden chest pain
- If you have or recently had a disease caused by blood clotting disorder (such as a tumor of the brain (meningioma)
- If you are suspected of having it

**Prevention of osteoporosis**
After the menopause some women develop fragile bones (osteoporosis). You may be advised to take calcium and vitamin D supplements. These are available for free from your local pharmacy if you have had your womb removed (hysterectomy). Women who have had both their womb and eggs removed (hysterectomy and oophorectomy) are more likely to have their bone density reduced (osteoporosis). Femoston prevents osteoporosis after menopause.

**Before you take Femoston**
Medical history and regular check-ups
The risk of a blood clot is considered when deciding whether to start taking it, or whether to carry on taking it. The estimated lifetime risks are greater for women with a premature menopause (due to ovaries failure) or who are taking HRT. The risk of a blood clot increases the more you are exposed to the risk factors of using HRT may be reduced if you:

- You are more likely to get a blood clot in your veins as you get older (increased risk of blood clotting disorder)
- You have a blood clotting disorder (such as polycythaemia, sickle cell disease or a blood disorder passed on by the parents)
- You have been suffering from blood clots in the arteries, such as a heart attack, stroke or aneurysm
- You have ever had a fever during treatment with Femoston (including those who have been treated for the condition with antibiotics)
- You have or are suspected of having a blood clotting disorder
- You have or are suspected of having a blood clotting disorder
- You have a blood clotting disorder (such as von Willebrand disease, a rare inherited blood disorder)
- You have an unusual bleeding tendency
- You have or have recently had a cancer which is sensitive to oestrogens
- You have a rare blood problem called "porphyria"
- You have ever had surgery, injury or illness (see also section 3, If you are seriously overweight (BMI >30 kg/m2)
- You may have a blood clotting disorder
- You have any of these situations applies to you:

**Effects of blood clots**

Bleeding and blood clots in a vein (thrombosis)
Bleeding and blood clots in a vein (thrombosis) or the lungs (pulmonary embolism) have been reported regularly in women who start using HRT. These blood clots may form in a vein (thrombosis) or the lungs (pulmonary embolism) and cause localised swelling and pain (thrombosis) or the lungs (pulmonary embolism). The risk of a blood clot varies with age. For example, in women aged 79 who are taking HRT over 5 years, there will be 13 to 20 cases in 1000 women. For women aged 50 to 79 who are not taking HRT, on average, over a 5-year period. For women who have been taking oestrogen-progestogen HRT over 5 years, there will be 11 to 13 cases in 1000 users (i.e. about 1 extra case).

Evidence suggests that taking combined oestrogen-progestogen HRT increases the risk of a blood clot. The risk of getting a blood clot with combined oestrogen-progestogen HRT has been associated with a slightly increased risk, compared to other treatments. The risk of blood clots in women who start using combined oestrogen-progestogen HRT is about 8 to 11 cases per 1000 users (i.e. about 1 extra case). For signs of a blood clot, see "Stop taking Femoston and consult your doctor immediately".

Looking for women in their 50s who are not taking HRT, on average, over a 5-year period. 4 to 5 women in 1000 would be expected to develop blood clots in a vein (thrombosis) or the lungs (pulmonary embolism). The risk of blood clots in those women taking oestrogen-progestogen HRT is about 3 to 5 cases per 1000 users (i.e. about 1 extra case).

Heart disease (heart attack)
Femoston protects you from this extra risk.

Breast cancer
Women over the age of 60 years who use oestrogen-progestogen HRT may be more likely to develop heart diseases than those not taking any HRT.

The risk of a heart attack is about 1.5 times higher in women taking oestrogen-progestogen HRT compared to women not taking any HRT. However, the number of extra cases of heart disease than those taking any HRT.

The risk of heart disease than those taking any HRT.

Other conditions
Evidence suggests that taking combined oestrogen-progestogen HRT increases the risk of breast cancer. The use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk, compared to other treatments. The risk of breast cancer varies with age. For example, in women aged 79 who are taking HRT over 5 years, there will be 13 to 20 cases in 1000 users (i.e. about 1 extra case).

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

 Pregnancy and breastfeeding
 Femoston must not be taken by pregnant women only. If you become pregnant, stop taking Femoston and contact your doctor.

 3. HOW TO TAKE FEMOSTON
 Always take Femoston exactly as your doctor has told you. You should always read the leaflet before you start taking the medicine and every time you get more medicine, in case there are any changes.

 Take one tablet every day, but not a break between packs. Swallow the tablet with water, or with food. Your doctor will arrange the shortest dose for the shortest time to treat your symptoms. Speak to your doctor if you think this dose is in strong or not enough. The usual starting dose is:

 During day 1 to 14 of the cycle, 1 tablet daily containing 1 or 2 mg medroxyprogesterone acetate immediately after the 28-day cycle you should begin the treatment with Femoston again.

 You will be taking Femoston on the back of the blister strips. The tablets from the pack with marked with arrow 1 should be taken in the 1st week of your cycle on the 1st day the pack with marked with arrow 2 should be taken. If you are not having periods and you are taking Femoston for any other Hormone Replacement Therapy (HRT), preparations, or you are switching from another continuous HRT product, you can start taking Femoston on any convenient day.

 If you are currently using a ‘cyclical’ or ‘sequential’ HRT product (which involves taking an estrogen tablet or patch for the first 14 days of the cycle, and progesterone 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 progestin 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 for the first time, you should inform your doctor immediately if the tablet colour is different to that of the ‘control’ tablet. The doctor will then increase the dose according to your symptoms. If you are taking Femoston to prevent osteoporosis, your treatment should begin with the dosage Femoston 1/10. Your doctor will increase this dose according to your symptoms. If you are taking Femoston for menopause (change of life), your treatment should begin with the dosage Femoston 1/40.

 If you are taking more than one Femoston tablet during the same cycle, a total of 4 mg medroxyprogesterone acetate (change of life), your treatment should begin with the dosage Femoston 1/40. Treatment for breast cancer may need to be continued for longer than the expected contraceptive effect of Femoston. In this case, you may need to continue to take Femoston for 4 weeks after your last dose of Femoston. If the symptoms persist, you should contact your doctor.