femoston®
estradiol/dydrogesterone

For patients who have been prescribed Femoston® 1/10 mg & 2/10mg

What is Femoston®

Femoston® is an oral Hormone Replacement Therapy (HRT).

It contains two types of female hormones, an oestrogen called estradiol and a progestogen called dydrogesterone.

Femoston® is indicated for oestrogen deficiency symptoms and for the prevention of osteoporosis in postmenopausal women at least 6 months since their last period.

What is oestrogen for?

During the menopause, oestrogen levels drop causing symptoms like hot flushes and night sweats.

Femoston® relieves these symptoms by replacing the oestrogen that the body is no longer producing.

What is progestogen for?

Women who have an intact womb need progestogen in their HRT.

Without it, oestrogen-only HRT could cause excessive thickening of the lining of the womb and increase the risk of womb cancer. The addition of progestogen reduces this extra risk.

When to take special care with Femoston®

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.

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.

Thrombosis

The risk of blood clots in the veins (thrombosis) 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. See your doctor immediately, if you notice possible signs of a thrombosis.

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:

- 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 (Hypericum perforatum).

Possible side effects

Like all medicines, Femoston® can cause side effects to some, although not everybody gets them. If you experience any side effects, or if you have any questions regarding your medication, please talk to your healthcare professional.

Once you have started on Femoston® you should see your doctor for regular check-ups at least once a year and go for regular breast screening, as recommended by your doctor.

Reporting side effects
For patients taking an Exeltis UK medicine: If you experience side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. By reporting side effects you can help provide more information on the safety of a medicine. Side effects can be reported to Exeltis UK Pharmacovigilance at pharmacovigilance.uk@exeltis.com. You can also report side effects to the MHRA via the Yellow Card Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.

This information is not intended to replace information provided by your healthcare professional.

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Exeltis
Rethinking healthcare.
Rethinking women's health.

Always take Femoston exactly as your doctor has told you.
You should check with your doctor or pharmacist if you are not sure.
Women new to HRT or those changing from a continuous HRT can start Femoston® on any day of the week.
Those changing from another sequential regimen can start once their current blister pack has finished.

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estradiol/dydrogesterone

How to take Femoston® 1/10mg

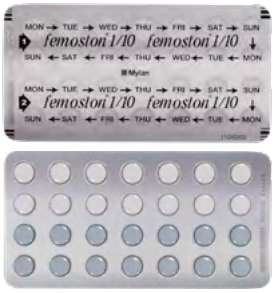
- **Only take one tablet every day**
- **Swallow the tablet with water**
- **Can be taken with or without food**
- **Try to take the tablet at the same time each day**
- **No break between packs**

DAYS 1-14 — The tablets from the section marked 1 (1) should be taken first. These contain oestrogen.

DAYS 15-28 — The tablets marked 2 (2) should be taken next. These contain progestogen as well as oestrogen. The tablets change colour to identify the addition of progestogen.

Please note that women will experience a withdrawal bleed towards the end of the 28 day cycle. In addition, women may have irregular bleeding or some spotting during the first 3-6 months of taking Femoston®. This usually settles over time.

Please speak to your doctor if you have any concerns.



DAY 1–14	Contains 1mg oestradiol
DAY 15–28	Contains 1mg oestradiol plus 10mg dydrogesterone

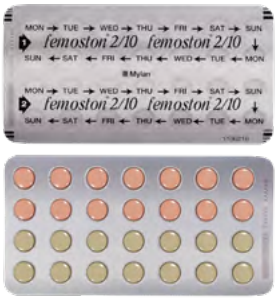
How to take Femoston® 2/10mg

- **Only take one tablet every day**
- **Swallow the tablet with water**
- **Can be taken with or without food**
- **Try to take the tablet at the same time each day**
- **No break between packs**

DAYS 1-14 — The tablets from the section marked 1 (1) should be taken first. These contain oestrogen.

DAYS 15-28 — The tablets marked 2 (2) should be taken next. These contain progestogen as well as oestrogen. The tablets change colour to identify the addition of progestogen.

Please note that women will experience a withdrawal bleed towards the end of the 28 day cycle. In addition, women may have irregular bleeding or some spotting during the first 3-6 months of taking Femoston®. This usually settles over time.



DAY 1–14	Contains 2mg oestradiol
DAY 15–28	Contains 1mg oestradiol plus 10mg dydrogesterone

Always read the patient information leaflet. If you forget to take your tablet at the usual time, take it within the next 12 hours. If more than 12 hours have gone by, start again as normal the next day. Do not take a double dose to make up for a forgotten tablet. Forgetting a dose may increase the likelihood of bleeding and spotting.

Reporting side effects
For patients taking an Exeltis UK medicine: If you experience side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. By reporting side effects you can help provide more information on the safety of a medicine. Side effects can be reported to Exeltis UK Pharmacovigilance at pharmacovigilance.uk@exeltis.com. You can also report side effects to the MHRA via the Yellow Card Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.

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