PACKAGE LEAFLET: INFORMATION FOR THE USER

Femoston continuous 0.5 mg/2.5 mg, film-coated tablets
estradiol/dydrogesterone

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet?
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? your doctor or pharmacist ..

Femoston Femoston continuous 0.5 mg/2.5 mg, film-coated tablets. In this leaflet, the abbreviated name Femoston is used.

Contents of this leaflet

1. WHAT IS FEMOSTON AND WHAT IS IT USED FOR?

This medicine is a so-called hormone replacement therapy (HRT). It contains two types of female hormones, estrogen called estradiol and progestogen called dydrogesterone. This medicine is intended for postmenopausal women who have not had a natural period for at least 12 months.

This medicine is used for: relief of postmenopausal symptoms
During menopause, the amount of estrogen in a woman's body decreases significantly. This can cause symptoms such as a warm feeling in the face, neck, and chest (“hot flashes”). This medicine relieves these symptoms after menopause. You will only be prescribed this medicine if your symptoms significantly limit your daily functioning.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

Medical history and regular check-ups
It is important to weigh the risks of hormone replacement therapy (HRT) against the benefits before starting this medicine or deciding to continue with it.

There is limited experience in treating women with premature menopause (due to ovarian problems or after surgery). If you have premature menopause, the risks of HRT use may be different. Discuss this with your doctor.

Before you start (or restart) HRT, your doctor will ask you some questions about your medical history and your family's medical history. Your doctor may decide to perform a physical examination and, if necessary, a breast examination and/or internal examination.
Once you have started this medicine, you should regularly go for check-ups with your doctor (at least once a year). During these check-ups, you will discuss the pros and cons of continuing the treatment.

Have a mammogram (X-ray) regularly, according to your doctor's advice.

When should you not use this medicine?
If any of the following situations apply to you, you should not use this medicine. If you are unsure, consult your doctor before starting the treatment.

Use this medicine not:
- if you have or have had breast cancer, or if breast cancer is suspected;
- if you have a malignant tumor that is sensitive to estrogen (e.g., a tumor of the endometrium or if it is suspected that you have this;
- if you have vaginal bleeding of unknown cause;
- if you have abnormal growth of the endometrium (endometrial hyperplasia) and you are not yet being treated for it;
- if you have or have ever had a blood clot in a vein (thrombosis) such as in the legs (deep vein thrombosis) or in the lungs (pulmonary embolism);
- if you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency);
- if you have recently had a blockage in an artery or if you currently have one, such as a heart attack, stroke, or angina pectoris (severe chest pain due to lack of oxygen);
- if you have or have ever had liver disease and your liver function has not yet recovered;
- if you have a congenital disorder in the production of red blood pigment (porphyria);
- if you have meningioma (a generally benign tumor of the tissue layer between the brain and the skull) or have ever been diagnosed with meningioma;
- if you are allergic to any of the ingredients in this medicine. These ingredients can be found in section 6.

If you develop any of the above conditions for the first time while using this medicine, you must stop using it immediately and contact your doctor.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before using this medicine if you have ever had or have had any of the conditions listed below, as they may recur or worsen during treatment with this medicine. If this is the case, you should visit your doctor more frequently for check-ups:
- a benign tumor in the uterus (also called a “fibroid”);
- a condition where the uterine lining is also found outside the uterus (endometriosis);
- abnormal growth of the uterine lining (endometrial hyperplasia);
- an increased risk of blood clots (see: ‘Blood clot in a vein (thrombosis)’);
- an increased risk of estrogen-sensitive cancer (for example, if your mother, sister, or grandmother has had breast cancer);
- a increased blood pressure;
- a liver condition such as a benign liver tumor;
- diabetes (diabetes);

- gallstones;
- migraine or severe headache;
- systemic lupus erythematosus (SLE; a specific disorder of the immune system that can occur in many parts of the body);
- epilepsy;
- asthma;
- an ear disorder with hearing loss (otosclerosis);
- an increased fat level in your blood (triglycerides);
- fluid retention due to heart or kidney problems;
- hereditary or acquired angioedema.

Meningioma
The use of Femoston has been associated with the development of a generally benign tumor of the tissue layer between the brain and the skull (meningioma). If you are diagnosed with meningioma, your doctor will treatment with Femoston discontinue. Tell your doctor immediately if you notice symptoms such as changes in vision (e.g., double vision or blurred vision), hearing loss or ringing in the ears, loss of smell, headache that worsens over time, memory loss, seizures, weakness in your arms or legs.

Stop using this medicine immediately and contact your doctor if any of the following situations occur while using HRT:
- any of the conditions under 'When should you not use this medicine?';
- yellowing of the skin or whites of the eyes (jaundice). This may be a sign of a liver disorder;
- symptoms of angioedema such as swelling of the face, tongue and/or throat and/or difficulty swallowing or a skin rash with pink bumps and severe itching (hives or welts), along with difficulty breathing;
- a significant increase in your blood pressure (symptoms include headache, fatigue, and dizziness);heid);
- migraine-like headache that you experience for the first time;
- become pregnant ;you notice signs of a blood clot, such as:
- painful swelling or redness of the legs,
    - sudden chest pain,swelling or redness of the legs,
    - sudden chest pain,
    - difficulty with breathing.

For more information, see ‘Blood clot in a vein (thrombosis)’.

Note: this medicine is not a contraceptive. If you have had a menstrual period in the last 12 months or are under 50 years old, you may still need to use contraceptives to prevent pregnancy. Consult your doctor for advice.

HRT and cancer
Abnormal growth of the uterine lining (endometrial hyperplasia) and cancer of the uterine lining (endometrial cancer)
Use of estrogen-only HRT increases the risk of abnormal growth of the uterine lining (endometrial hyperplasia) and cancer of the uterine lining (endometrial cancer). The hormone progestogen in this medicine protects against this additional risk.

Irregular bleeding

You may experience irregular bleeding or spotting during the first 3-6 months of treatment. However, if the irregular bleeding:
- persists beyond the first 6 months
- starts after you have been using this medicine for more than 6 months
- continues after you have stopped this medicine

you should contact your doctor as soon as possible.

Breast cancer
Research has shown that the use of hormone replacement therapy (HRT) with an estrogen-progestogen combination or estrogen-only HRT increases the risk of breast cancer. The additional risk depends on how long you use HRT. The additional risk occurs after 3 years of use. After stopping HRT, the additional risk will decrease again, but if you have used HRT for more than 5 years, the additional risk may persist for 10 years or longer.

Comparison
Among women aged 50 to 54 who do not use HRT, an average of 13 to 17 per 1,000 women will develop breast cancer over a 5-year period.
Among women aged 50 who use estrogen-only HRT for 5 years, there will be 16-17 cases per 1,000 users (i.e., 0 to 3 extra cases).
Among women aged 50 who start HRT with an estrogen-progestogen combination over a 5-year period, there will be 21 cases per 1,000 users (i.e., 4 to 8 extra cases).
Among women aged 50 to 59 who do not use HRT, an average of 27 per 1,000 women will develop breast cancer over a 10-year period.
Among women aged 50 who use estrogen-only HRT for 10 years, there will be 34 cases per 1,000 users (i.e., 7 extra cases).
Among women aged 50 who use estrogen-progestogen combination HRT for 10 years, there will be 48 cases per 1,000 users (i.e., 21 extra cases).

Regularly check your breasts. Contact your doctor if you notice any changes such as:
- dimpling of the skin;
- changes of the nipple;
- lumps that you can see or feel.

Additionally, it is recommended to participate in breast cancer screening when offered. For breast examination (mammography), it is important to inform the nurse/healthcare provider conducting the X-ray that you are using HRT, as these medications can increase the density of your breasts and thus affect the results of the examination. In areas where breast density is increased, mammography may not detect all lumps.

Ovarian cancer
Ovarian cancer is rare, much rarer than breast cancer. A slight increase in the risk of ovarian cancer has been reported with the use of estrogen therapy or a combination of estrogen/progestogen HRT.

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

HRT and effects on heart and circulation

Blood clot in a vein (thrombosis)
Women using HRT have about 1.3 to 3 times higher risk of developing a blood clot in the veins than women not using HRT, especially during the first year of treatment.

A blood clot can be serious, and if it reaches the lungs, it can lead to chest pain, shortness of breath, fainting, and even death.

The risk of a blood clot increases as you get older and if any of the following situations apply to you. Inform your doctor in the following cases:
- you are unable to walk for a long time due to surgery, injury, or illness (see also section 3 'If you need to have surgery');
- you are severely overweight (BMI >30 kg/m^2);
- you have a blood clotting disorder for which you need to take medication long-term to prevent blood clots;
- one of your close relatives has ever had a blood clot in the legs, lungs, or another organ;
- you have systemiclupus erythematosus (SLE);
- you have cancer.

For signs of a blood clot, see 'Stop using this medicine immediately and contact your doctor'.

Comparison
Of the women in their fifties who do not use HRT, an average of 4 to 7 out of 1,000 will develop a blood clot over a 5-year period.
Of the women in their fifties who use HRT with estrogen and progestogen for more than 5 years, there are between 9 and 12 cases per 1,000 (i.e., 5 extra cases per 1,000).

Heart disease (heart attack)
There is no evidence that HRT helps prevent a heart attack. Women over 60 who use HRT with estrogen and progestogen have a slightly higher risk of developing heart disease than women who do not use HRT.

Stroke
The risk of stroke is about 1.5 times higher in women who use HRT than in women who do not use HRT. The number of extra cases of stroke due to HRT increases with age.

Comparison
Of the women in their fifties who do not use HRT, an average of 8 out of 1,000 will have a stroke over a 5-year period. Among women in their fifties who use HRT, there are 11 cases of stroke per 1,000 users over a 5-year period (i.e., 3 extra cases per 1,000).

Other conditions
HRT does not prevent memory loss. There is evidence that there is a higher risk of memory loss in women who start using HRT after the age of 65th year. Ask your doctor for advice.
Inform your doctor if you suffer from, or have suffered from, any of the following conditions. Your doctor will you then more often monitor:
- heart disease
- kidney dysfunction
- increased levels of fats in your blood (hypertriglyceridemia).

Children and adolescents up to 18 years
This medicine is not intended for use by children.

Are you using any other medicines?
Are you using any other medicines besides Femoston, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Some medicines can reduce the effectiveness of Femoston, causing you to have irregular bleeding. This applies to:
- medicines for epilepsy (such as phenobarbital, phenytoin, carbamazepine),
- medicines for tuberculosis (such as rifampicin, rifabutin),
- medicines against an HIV infection [AIDS] (such as nevirapine, efavirenz, ritonavir,and nelfinavir),
- herbal remedies containing St. John's wort (Hypericum perforatum).

HRT can affect the action of some other medicines:
- a medicine for epilepsy (lamotrigine), because this can increase the frequency of epileptic seizures;
- the hepatitis C virus (HCV) combination treatments ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin;glecaprevir/pibrentasvir or glecaprevir/pibrentasvirALT liver enzyme) in women using combined hormonal contraceptives containing ethinylestradiol. Femoston contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when Femoston is used with this HCV combination treatment.buvir/velpatasvir/voxilaprevir can cause an increase in liver function blood values (increase of doctor hormonal contraceptives containing ethinylestradiol. Femoston contains estradiol instead of ethinylestradiol. It is not known whether an increase in ALT liver enzyme can occur when Femoston is used with this HCV combination treatment. advise you. Are you using any other medicines besides Femoston, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription, herbal medicines, or other natural products. you advise.

Are you using any other medications besides Femoston, have you done so recently, or are you planning to do so soon? If so, inform your doctor or pharmacist. This also applies to medications you can obtain without a prescription, herbal medicines, or other natural products.

Laboratory tests
If your blood is being tested, you must tell the doctor or lab technician that you are using this medicine, as it can affect the results of some tests.

What should you pay attention to with food?
This medicine can be taken with or without food.

Pregnancy and breastfeeding
This medicine is intended for use only by women after menopause.

If you become pregnant ,

stop using this medicine immediately and contact your doctor.

This medicine is not intended for use during the breastfeeding period.

Driving and using machines
The effect of this medicine on driving or using machines has not been studied. An effect is unlikely.

Femoston tablets contain lactose.
If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

When should you start taking this medicine?
Do not take this medicine earlier than 12 months after the last natural menstruation.
You can start this medicine on any desired day if you:
- are not currently taking an HRT medicine.
- are switching from a continuous combined HRT medicine. This is when you use a tablet or patch every day that contains both an estrogen and a progestogen.

You can start this medicine the day after the end of the 28-day cycle if you:
- are switching from a 'cyclic' or 'sequential' HRT medicine. This is the case if you take a tablet or use a patch containing estrogen in the first part of your cycle. Then for 14 days, you take a tablet or use a patch with both an estrogen and a progestogen.

The use of this medicine
- Take the tablet with water.
- You can take the tablet with or without food.
- Try to take the tablet at approximately the same time every day. This ensures a constant amount of the medicine in your body. It will also help remind you to take your tablets.
- Take one tablet every day without a break between the packs. The strips are marked with the days of the week to make it easier for you to remember when to take your tablets.

Explanation day indication on the strips:

MO	=	Monday
TU	=	Tuesday
WE	=	Wednesday
TH	=	Thursday
FR	=	Friday
SA	=	Saturday
SU	=	Sunday

How much should I take?

Your doctor aims to prescribe you the lowest possible dose to treat your symptoms, for the shortest possible period. Discuss with your doctor if you think the dose is too high or too low.

Take 1 yellow-colored tablet per day during a cycle of 28 days.

If you need to undergo surgery
If you need to undergo surgery, tell the doctor that you are using this medicine. You should stop using this medicine about 4 to 6 weeks before the surgery to reduce the risk of a blood clot (see section 2, 'Blood clot in a vein (thrombosis)'). Ask your doctor when you can start using this medicine again.

Have you taken too much of this medicine?
If you or someone else takes too much of this medicine, it is unlikely to cause harm. You may feel nauseous (unwell) or vomit, have tender or painful breasts, feel dizzy, have abdominal pain, feel drowsy/tired, or experience withdrawal bleeding. No treatment is necessary, but if you are concerned, you can ask your doctor for advice.

Have you forgotten to take this medicine?
Take the forgotten tablet as soon as you remember. If more than 12 hours have passed since you should have taken your tablet, take the next dose at the usual time and do not take the forgotten tablet. Do not take a double dose to make up for a forgotten dose. If you miss a dose, bleeding or spotting may occur.

If you stop taking this medicine
Do not stop taking this medicine without prior consultation with your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following conditions have been reported more frequently in women using HRT than in women not taking HRT:

- breast cancer
- abnormal growth or cancer of the endometrium (endometrial hyperplasia or cancer)ovarian cancer
- ovarian cancer
- blood clot in a vein in the legs or lungs (venous thromboembolism)
- heart disease
- stroke
- possible memory loss when HRT is started after the age of 65[e] years.

See section 2 for more information about these side effects.

The following side effects may occur with this medicine:
Very common (occur in more than 1 in 10 users):

- headache

- abdominal pain
- back pain
- tender or painful breasts.

Common (occur in less than 1 in 10 users):
- vaginal thrush (a vaginal infection caused by a fungus called Candida albicans is called)
- depressive feelings, nervousness
- migraine; if you experience a migraine-like headache for the first time, stop taking this medicine and contact your doctor immediately
- dizziness
- nausea; vomiting;
- bloating (swelling of the abdomen) including flatulence
- allergic skin reactions (such as rash, severe itching (pruritus) or hives (urticaria))
- abnormal bleeding patterns, such as irregular bleeding, spotting, painful menstruation (dysmenorrhea), heavier or lighter bleeding
- pain in the pelvis
- cervical discharge
- feeling of weakness, fatigue or malaise
- swelling of the ankles, feet or fingers (peripheral edema)
- weight gain.

Sometimes (occur in less than 1 in 100 users):
- cystitis-like symptoms
- increase in the size of tumors in the uterus (fibroidshypersensitivity reactions such as shortness of breath (allergic asthma)
- changed
- desire for sex blood clots in the legs or lungs (venous thromboembolism or pulmonary embolism)
- blood clots in the legs or lungs (venous thromboembolism or pulmonary embolism)
- blood pressure (hypertensionhypertensionenlarged and
- twisted veins (varicose veins)
- enlarged and twisted veins (varicose veins)
- poor digestion
- liver disorders, sometimes with yellowing of the skin (jaundice), feeling of weakness (asthenia) or general feeling of being unwell (malaise) and abdominal pain. If you notice that your skin or the whites of your eyes turn yellow, stop taking Femoston and contact your doctor immediately.
- disorder of the gallbladder
- swelling of the breasts
- premenstrual syndrome (PMS)
- weight loss.

Rare (occur in less than 1 in 1,000 users):
*Side effects reported from the market that were not observed in clinical studies are also under the frequency “rare”).
- disease resulting from the destruction of red blood cells (hemolytic anemia)*
- meningioma (a brain tumor)*
- change in the surface of the eye (steepening of the corneal curvature)*;
- unable to wear your contact lenses (contact lens intolerance)*
- heart attack (myocardial infarction)

- stroke*
- swelling of the skin of the face and throat. This can cause breathing difficulties (angioedema)
- purplish spots or petechiae on the skin (vascular purpura)
- painful reddish skin nodules (erythema nodosum)*, discoloration of the skin especially on the face or neck, known as “pregnancy masks” (chloasma or melasma)*
- leg cramps*.

The following side effects have been reported with HRT products:
- benign and malignant tumors influenced by the amount of estrogens, such as cervical cancer and ovarian cancer (see section 2 for more information)
- increase in tumor growth due to the amount of progestogens (such as meningioma)
- a disease of the immune system that affects many organs in the body (systemic lupus erythematosus)
- possible dementia
- worsening of seizures (epilepsy)
- involuntary muscle contractions (chorea)
- blood clots in the arteries (arterial thromboembolism)
- inflammation of the pancreas (pancreatitis) in women who already had a high level of certain fats in the blood (hypertriglyceridemia)
- skin rash with disc-shaped red or painful spots (erythema multiforme)
- urinary-incontinence
- painful/lumpy breasts (fibrocystic breast condition)
- erosion of the cervix (uterine cervical erosion)
- exacerbation of a rare blood pigment disease(porphyria)
- high levels of certain fats in the blood (hypertriglyceridemia)
- increased level of total thyroid hormone.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.
There are no special storage conditions for this medicine.
Do not use this medicine after the expiry date. It can be found on the label on the packaging after “EXP:”. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

The active substances in this medicine are estradiol as estradiol hemihydrate and dydrogesterone.
Each tablet contains 0.5 mg estradiol as estradiol hemihydrate and 2.5 mg dydrogesterone.
The other substances in the tablet core are lactose monohydrate, hypromellose, corn starch, colloidal silicon dioxide (anhydrous) and magnesium stearate.
The other ingredients in the film coating are titanium dioxide (E171), yellow iron oxide (E172), polyvinyl alcohol, macrogol 3350, talc.

What does Femoston continuous 0.5 mg/2.5 mg look like and how many are in a package?
This medicine is a film-coated tablet. The tablet is round, yellow, and biconvex and marked on one side with "379". Each strip contains 28 tablets.
The tablets are yellow.
The tablets are packaged in PVC/Aluminum blister strips.
The blister packs contain 28 film-coated tablets.

Holder of the marketing authorization and manufacturer for placing on the market
Registration holder:
Euro Registratie Collectief b.v.
Kempkens 2200
5465 PR Veghel

Repacker (see label on the outer packaging):
Brocacef B.V., Maroastraat 43, 1060 LG Amsterdam
or
Stephar B.V., Kempkens 2200, 5465 PR Veghel

Manufacturer
Abbott Biologicals B.V.
C.J. van Houtenlaan 36
1381 CP Weesp

Registered under:
RVG 126241//103887 Femoston continuous 0.5 mg/2.5 mg, film-coated tablets (Austria)

The product from this leaflet is marketed in the country of origin under the name
Austria: Femoston conti 0.5 mg/2.5 mg Film-coated tablets

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