PACKAGE LEAFLET: INFORMATION FOR THE USER

Femoston conti 1/5, film-coated tablets 1 mg, 5 mg
active substances: estradiol/dydrogesterone

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.Keep this leaflet. You may need to read it again.
- Do you have any questions? Please 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 mentioned in this leaflet?
- Then contact your doctor or pharmacist ..

Contents of this leaflet

What is Femoston and what is it used for?
1. When should you not use this medicine or be extra careful with it?
2. How should you use this medicine?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

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

Femoston 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.

Femoston 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"). Femoston relieves these symptoms after menopause. You will only be prescribed this medicine if your symptoms significantly limit your daily functioning.

Prevention of bone loss
After menopause, some women may develop brittle bones (osteoporosis). Your doctor will discuss the various treatments with you.
If you are at increased risk of fractures due to bone loss and other medications are not suitable for you, you can use Femoston to prevent bone loss after menopause.

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 several questions about your medical history and that of your family. Your doctor may decide to perform a physical examination and, if necessary, a breast exam and/or internal examination.

Once you have started with Femoston, you should regularly visit your doctor for check-ups (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) taken regularly, according to your doctor's advice.

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

Do not use this:
- 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 for which the cause has not been determined;
- 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 returned to normal;
- 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 substances can you find in section 6.

If you experience 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 taking this medicine if you have or have ever 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 known as a 'fibroid');

- a condition where the uterine lining is also found in places 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);
- an increased blood pressure;
- a liver disorder 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 content in your blood (triglycerides);
- fluid retention as a result of heart or kidney problems;
- hereditary or acquired angioedema.

Stop using this medicine immediately and contact your doctor
if any of the following situations occur while using HRT:

- one of the conditions under "When should you not use this medicine?";
- yellowing of the skin or the 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);
- migraine-like headache that you experience for the first time;
- you become pregnant;you notice signs of a blood clot, such as:
- painful swelling or redness of the legs,
    - sudden chest pain,
    - difficulty
    - with breathing ..

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

Note: Femoston is not a contraceptive. If you have had a period in the last 12 months or are under 50 years old, you may still need to use contraceptives to prevent pregnancy. Ask 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 HRT with estrogen alone 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 small amounts of blood loss ('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 Femoston for more than 6 months
- persists afteryou have stopped using Femoston

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 HRT with estrogen alone 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
Of 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.
Of women aged 50 who use HRT with estrogen alone for 5 years, there will be 16-17 cases per 1,000 users (i.e., 0 to 3 extra cases).
Of 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).
Of 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.
Of the 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).
Of the women aged 50 who use combined estrogen-progestogen 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 anychange 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 performing the X-ray that you are using HRT because these medicines can increase the density of your breasts and thus affect the result 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. Of the women aged 50 to 54 who do not use HRT, about 2 in 2,000 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 2,000 users (i.e., about 1 extra case).

HRT and effects on heart and circulation
Blood clot in a vein (thrombosis)
Women who use HRT have about a 1.3 to 3 times higher chance of developing a blood clot in the veins than women who do not use 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 period due to surgery, injury, or illness (see also section 3 "If you need to undergo surgery").
- you are severely overweight (BMI >30 kg/m^2).
- you have a blood clotting disorder for which you need to use 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 period of 5 years.
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 years old who use HRT with estrogen and progestogen have a slightly higher chance 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 period of 5 years. Among women in their fifties who use HRT, there are 11 cases of stroke per 1,000 users over a period of 5 years (i.e., 3 extra cases per 1,000).

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 stop your treatment with Femoston. Inform 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, headaches that worsen over time, memory loss, seizures, weakness in your arms or legs.

Other conditions

HRT does not work to prevent memory loss. There is evidence that there is a greater chance of memory loss in women who start using HRT after their 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 then more often check:
- heart disease
- renal impairment
- increased levels of fats in your blood (hypertriglyceridemia).

Children
Femoston 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? If so, 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, carbamazepine, phenytoin),
- medicines for tuberculosis (such as rifampicin, rifabutin),
- medicines for the treatment of HIV infection [AIDS] (such as nevirapine, efavirenz, ritonavir, and nelfinavir),
- herbal medicines containing St. John's wort (Hypericum perforatum).

HRT can affect the action of some other medicines:
- a medicine for epilepsy (lamotrigine), because it 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 sofosbuvir/velpatasvir/voxilaprevir can cause an increase in liver functionblood values (increase of ALT 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. Your doctor will advise you..

medicines you can obtain without a prescription, herbal medicines, or other natural products.
Laboratory tests

Laboratory tests
If your blood is being tested, you must inform the doctor or lab technician that you are using Femoston, as it may affect the results of some tests.

What should you pay attention to with food and drink?
Femoston can be taken with or without food.

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

If you become pregnant stop taking Femoston immediately and contact your doctor.
It is not intended to use Femoston during the breastfeeding period.

Driving and using machines

The effect of Femoston 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.
If your doctor has informed you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

When to start taking Femoston

Do not start taking Femoston earlier than 12 months after the last natural menstruation.
You can start Femoston on any desired day

if you: start with Femoston if you:
currently not taking any HRT medication.
are switching from a continuous combined HRT product. This is if you use a tablet or patch every day that contains both estrogen and progestogen.

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

Het use of this medication
Take the tablet with water.
You can take the tablet with or without food.
Try to take the tablet at about the same time every day. This ensures a constant amount of the medication in your body. It will also help remind you to take your tablets.
Take one tablet every day without a break between 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 of the day indication:

German		Portuguese		Dutch
MO	=	Seg	=	Monday
DI	=	Ter	=	Tuesday
MI	=	Qua	=	Wednesday
DO	=	Qui	=	Thursday
FR	=	Fri	=	Friday
SA	=	Sat	=	Saturday
SO	=	Sun	=	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. If you are using Femoston to prevent osteoporosis, your doctor will adjust the dosage to suit you. That depends on your your body mass.
Take 1 salmon-colored tablet per day for a cycle of 28 days.

If you need to undergo surgery
If you need to undergo surgery, tell the doctor that you are using Femoston. 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 many Femoston tablets, it is unlikely to cause harm. You may feel nauseous (unwell) or vomit, have tender or painful breasts, feel dizzy, have abdominal pain, feel sleepy/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 missed 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 missed tablet. Do not take a double dose to make up for a missed dose. If you miss a dose, bleeding or spotting may occur.

If you stop taking this medicine
Do not stop taking Femoston without consulting 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 who used HRT than inwomen who do not take HRT:

- breast cancer
- abnormal growth or cancer of the lining of the womb (endometrial hyperplasia or 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 (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 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 Femoston and contact your doctor immediately
- dizziness
- nausea; vomiting; flatulence (flatulence)
- allergic skin reactions (such as rash, severe itching (pruritus), or hives (urticaria))
- abnormal bleeding patterns, such as irregular bleeding, light bleeding (spotting), painful menstruation (dysmenorrhea), heavier or lighter bleeding
- pain in the pelvis
- discharge from the cervix (cervical discharge)
- feeling of weakness, fatigue, or being unwell
- swelling of the ankles, feetor fingers (peripheral edema)
- weight gain.

Sometimes (may occur in up to 1 in 100 patients):
- cystitis-like symptoms
- increase in the size of tumors in the uterus (fibroids)
- hypersensitivity reactions such as shortness of breath (allergic asthma) or other reactions that can occur throughout the body, such as nausea, vomiting, diarrhea, or low blood pressure
- changed desire for sex
- blood clots in the legs or lungs (venous thromboembolism or pulmonary embolism)
- high blood pressure (hypertension)
- problems with blood circulation (peripheral vascular disease)
- 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 (may occur in up to 1 in 1,000 patients):
∗ Side effects reported from the market that were not observed in clinical studies are also classified under the frequency “rare”).
- disease as a result of the destruction of red bloodcells (hemolytic anemia)*
- meningioma (a brain tumor)*
- change of the eye surface (steepening of the corneal curvature)*; unable to wear your contact lenses (intolerance to contact lenses)*
- 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 spots” (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 spasms (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)
- urinaryincontinence
- painful/lumpy breasts (fibrocystic breast disease)
- erosion of the cervix (uterine cervical erosion)
- worsening of a rare disease of the blood pigment (porphyria)
- high levels of certain fats in theblood (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. This 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 1 mg estradiol as estradiol hemihydrate and 5 mg dydrogesterone.
The other substances in the tablet core are lactose monohydrate, hypromellose, maize starch, colloidal silicon dioxide (anhydrous), and magnesium stearate.
The other substances in the film coating are titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), hypromellose, macrogol.

What does Femoston conti 1/5 look like and what is in a package?
This medicine is a film-coated tablet. The tablet is round, salmon-colored, and biconvex and marked with "379" on one side (diameter 7 mm). Each strip contains 28 tablets. The tablets are packed in PVC/Aluminum blister strips. The blister packs contain 28 or 84 (3 x 28) film-coated tablets.

Marketing authorization holder:
Marketing Authorization Holder:
Euro Registration Collective 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
(RVG 28349//25549)
Abbott Biologicals BV
Veerweg 12
8121 AA Olst
Netherlands

(RVG 135804//25549)
Abbott Biologicals BV
1381 CP Weesp
Netherlands

Registered under
RVG 135804//25549 Femoston conti 1/5, film-coated tablets 1 mg, 5 mg (Austria)
RVG 28349//25549 Femoston conti 1/5, film-coated tablets 1 mg, 5 mg (Portugal)

The product from this leaflet is marketed in the country of origin under the name: Austria:
Femoston conti 1 mg/5 mg
Portugal: Femoston 1/5

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