PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Femoston-conti 0.5 mg/2.5 mg
Film-coated Tablets

Active substances and their quantity:
Each film-coated tablet contains a combination of estradiol and dydrogesterone:
Estradiol 0.5 mg
Dydrogesterone 2.5 mg

Femoston-conti 1 mg/5 mg
Film-coated Tablets

Active substances and their quantity:
Each film-coated tablet contains a combination of estradiol and dydrogesterone:
Estradiol 1 mg
Dydrogesterone 5 mg

For a list of inactive and allergenic ingredients in the medicine – please see section 6 ("Further information").

Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?
Femoston-conti 0.5 mg/2.5 mg
Hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women, who are at least 12 months after their last menstrual period.
Intended for women with a normal uterus.
Experience in treating women over the age of 65 is limited.
Femoston-conti 1 mg/5 mg
Hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women, who are at least 12 months after their last menstrual period.
Prevention of osteoporosis in postmenopausal women who are at increased risk for fractures, in which other medicines for prevention of osteoporosis are contraindicated or are not tolerated by them.
Intended for women with a normal uterus.
Experience in treating women over the age of 65 is limited.
Therapeutic group: Sex hormones, progestogens and estrogens, for continuous therapy.

2. BEFORE USING THE MEDICINE
Do not use Femoston-conti if:
- You have or have had **breast cancer**, or if there is a suspicion that you have breast cancer
- You have **cancer which is sensitive to estrogens**, such as cancer of the uterine lining (endometrium), or if you are suspected of having such a cancer
- You have **any unexplained vaginal bleeding**
- You have **excessive thickening of the uterine lining** (endometrial hyperplasia)
- 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)
- You have **a blood clotting disorder** (such as deficiency in protein C, protein S, or antithrombin deficiency)
- You have or have recently had a disease caused by blood clots in the arteries, such as **a heart attack, stroke or angina**
- You have or have had **a liver disease** and your liver function test results have not returned to normal values
- You have a rare inherited blood problem called "porphyria"
- You are **sensitive (allergic)** to estradiol, dydrogesterone or to any of the other ingredients contained in the medicine. For a list of the inactive ingredients, see section 6 "Further information".

Special warnings regarding use of the medicine
The preparation is intended for the treatment of symptoms, and not to prevent them.
If you have been treated with the preparation Femoston-conti for 3 months and have not noticed an improvement in the symptoms, you should return to the doctor.
Before treatment with Femoston-conti, tell the doctor if you have suffered in the past from any of the effects described below, as they may reoccur or become worse during treatment with Femoston-conti. In such a case, you should be examined by your doctor more frequently:
- Uterine fibroids.
- Growth of uterine lining outside the uterus (endometriosis) or a history of excessive growth of the uterine lining (endometrial hyperplasia).
- A brain tumor that may be affected by the levels of progestogens (meningioma).
- Increased risk of developing blood clots [for further information, see later on in the leaflet in "Blood clots in a vein (thrombosis)"].
- Increased risk of getting an estrogen-sensitive cancer (such as a mother, sister or grandmother who has had breast cancer).
- Hypertension.
- A liver disorder such as a benign liver tumor.
- Diabetes.
- Gallstones.
- Migraine or severe headaches.
- A disease in which the immune system abnormally attacks many organs in the body [systemic lupus erythematosus, SLE (lupus)].
- Epilepsy.
- Asthma.
- A disease affecting the eardrum and hearing (otosclerosis).
- High blood lipid levels (triglycerides).
- Fluid retention due to heart or kidney problems.

Stop taking Femoston-conti and see a doctor immediately if you notice any of the following conditions while taking hormone replacement therapy:
- Any of the conditions mentioned in the section "Do not use Femoston-conti if:"
- Yellowing of the skin or the whites of the eyes (jaundice). These may be signs of a liver disease.
- A large increase in blood pressure (symptoms may be: headache, tiredness, dizziness).
- Migraine-like headaches, which occur for the first time.
- If you become pregnant.
- If you notice signs of blood clots, such as painful swelling and redness of the legs, sudden chest pain, difficulty in breathing. For further information, see "Blood clots in a vein (thrombosis)" discussed further on in the leaflet.

Note: Femoston-conti is not a contraceptive. If less than 12 months have passed since your last menstrual period or you are under the age of 50, you may still need to use additional contraceptive methods to prevent pregnancy. Consult your doctor about this.
Hormone replacement therapy and cancer
Excessive thickening of the uterine lining (endometrial hyperplasia) and endometrial cancer:
Taking estrogen-only hormone replacement therapy will increase the risk of excessive thickening of the uterine lining and endometrial cancer. The progestogen in Femoston-conti protects you from this extra risk.
Abnormal vaginal bleeding
You may have light bleeding or spotting for the first 3-6 months of taking Femoston-conti. However, if the abnormal bleeding:
- lasts beyond the first 6 months
- begins after you have been taking Femoston-conti for more than 6 months
- continues after you stop taking Femoston-conti

Contact your doctor as soon as possible.
Breast cancer
Evidence indicates that taking estrogen-progestogen combined, and possibly also estrogen-only hormone replacement therapy increases the risk of breast cancer. The increased risk depends on the duration of time that you take hormone replacement therapy. The additional risk can be assessed after several years of treatment with the preparation. The risk returns to normal in the population within about 5 years after stopping treatment.
Comparison
For women aged 50-79 who are not taking hormone replacement therapy, on average 9-17 out of 1,000 women will be diagnosed with breast cancer over a 5-year period.
For women aged 50-79 who are taking estrogen-progestogen hormone replacement therapy over a period of 5 years, there will be an average of 13-23 women out of 1,000 with breast cancer (meaning an additional 4 to 6 cases).
Check your breasts regularly. See your doctor if you notice any changes such as:
- dimpling of the skin
- changes in the nipple
- lumps you can see or feel

In addition, it is recommended that you join mammography screening programs when they are offered to you. When undergoing a mammogram, it is important that you inform the nurse or the medical staff member who is performing the screening that you are using hormone replacement therapy. This is because the treatment may increase the density of your breasts, which may affect the results of the test. When breast density is increased, not all lumps may be detected in a mammogram.
Ovarian cancer
Ovarian cancer is rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen hormone replacement therapy has been associated with a slightly increased risk of ovarian cancer. The risk of ovarian cancer varies with age. For example, in women aged 50-54 who are not taking hormone replacement therapy, about 2 women in 2,000 will be diagnosed with ovarian cancer over a 5-year period. In women who take hormone replacement therapy for 5 years, there will be about 3 cases out of 2,000 women taking it (meaning about one additional case).
Effect of hormone replacement therapy on heart and blood circulation
Blood clots in a vein (thrombosis)
The risk **of blood clots in the veins** is about 1.3 to 3 times higher in women taking hormone replacement therapy than in women who do not take this treatment, especially during the first year of use. Blood clots can be severe, and if a blood clot reaches the lungs, it can cause chest pain, shortness of breath, fainting and even death.
The likelihood of developing a blood clot in the veins increases with age, as well as if any of the following apply to you.
Inform your doctor if one or more of the following conditions apply to you:
- You are unable to walk for a long time due to major 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 problem that requires long-term treatment with a medicine used to prevent blood clots
- If one of your close relatives has had a blood clot in the leg, lung or any other organ
- You have systemic lupus erythematosus (lupus)
- You have cancer

  For signs of a blood clot, see section 2 "Stop taking Femoston-conti and see a doctor immediately".

Comparison
Looking at women in their 50s who do not take hormone replacement therapy, on average 4-7 out of 1,000 women are expected to develop blood clots in the veins over a 5-year period. In women in their 50s who are taking estrogen-progestogen hormone replacement therapy over a 5-year period, there will be 9-12 cases out of 1,000 (meaning 5 additional cases).
Heart diseases (heart attack)
There is no evidence that hormone replacement therapy will prevent a heart attack. Women over the age of 60 who take estrogen-progestogen hormone replacement therapy are slightly more likely to develop heart disease than women who do not take hormone replacement therapy.
Stroke
The risk of stroke is 1.5 times higher in women taking hormone replacement therapy than those not taking this therapy. The number of additional cases of stroke following use of the therapy increases with age.
Comparison
When looking at women in their 50s who do not take hormone replacement therapy, an average of 8 out of 1,000 women are expected to experience stroke in a 5-year period. In women in their 50s who take hormone replacement therapy over a 5-year period, 11 cases out of 1,000 are expected (meaning 3 additional cases).
Additional conditions
Hormone replacement therapy will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who begin hormone replacement therapy after the age of 65. Consult with your doctor.
Tell the doctor if you are suffering from or have suffered in the past from any of the following medical conditions, since he will need to monitor you more frequently:
- **Heart diseases**
- **Kidney problems**
- **Higher than normal levels of certain blood lipids (hypertriglyceridemia)**

Children and adolescents
Femoston-conti is not intended for use in children and adolescents.
Tests
Once you have started treatment with Femoston-conti, you should see your doctor for periodic checkups (at least once a year).
If you need to have laboratory tests performed, tell your doctor or the laboratory staff that you are taking Femoston-conti, since this medicine could affect the results of some tests.
Drug Interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines or other natural products, and nutritional supplements, tell the doctor or pharmacist.
Some medicines may interfere with the activity of Femoston-conti. This might lead to abnormal 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 infections (AIDS) (such as ritonavir, nelfinavir, nevirapine, efavirenz)
- Herbal medicines containing the herb St. John's wort (Hypericum perforatum)

Use of the medicine and food
Femoston-conti can be taken with or without food.
Pregnancy and breastfeeding
Femoston-conti is intended for postmenopausal women only. If you become pregnant, stop taking Femoston-conti and contact the doctor. Femoston-conti is not intended for use during breastfeeding.
Driving and using machinery
Femoston-conti has negligible or no impact on driving or using machines.
Important information about some of the ingredients of the medicine
Femoston-conti contains lactose. If you have been told by the doctor that you have an intolerance to any sugars, consult the doctor before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions. You should check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.
When to start taking Femoston-conti:
Do not start taking Femoston-conti until at least 12 months have passed since your last natural menstrual period.
You can start taking Femoston-conti on any day that suits you if:
- You are not currently taking any preparation for hormone replacement therapy.
- You are switching from a preparation of hormone replacement therapy that is "continuous combined", meaning you take a tablet every day or use a patch that contains both an estrogen and a progestogen together.

Start taking Femoston-conti the day after you finish the 28-day cycle if:
- You are switching from another hormone replacement therapy preparation that is "cyclic" or "continuous". Meaning you take a tablet or use a patch that contains estrogen for the first part of the cycle, and then take a tablet or use a patch that contains both an estrogen and a progestogen together, for up to a period of 14 days.

How to take the medicine
- Swallow the tablet with water.
- You can take the tablet with or without food.
- There is no information regarding crushing/halving/chewing.
- Try to take the tablet at the same time every day. This is to ensure that there is a fixed amount of the medicine in your body. This will also help you remember to take the tablets.
- Take one tablet every day without a break between packs. The blisters are marked with the days of the week. This will make it easier for you to remember when to take the tablets.
- Your doctor aims to give you the lowest dose, for the shortest amount of time, to treat your symptoms. Talk to your doctor if you think the dose is too high or not high enough.
- If you are taking Femoston-conti 1 mg/5 mg to prevent osteoporosis, the doctor will adjust the dose according to your bone density.
- Take one tablet every day for a 28-day cycle.

If you are about to undergo surgery, tell the surgeon that you are taking Femoston-conti. You may need to stop taking Femoston-conti about 4-6 weeks before the operation to reduce the risk of blood clots [see section 2 "Blood clots in a vein (thrombosis)"]. Ask the doctor when you can resume taking Femoston-conti.
Do not exceed the recommended dose
If you have accidentally taken a higher dosage than necessary, or if you or someone else took too many Femoston-conti tablets, it is unlikely that they will be harmed. You may experience nausea, vomiting, chest sensitivity, dizziness, abdominal pain, drowsiness/tiredness, and withdrawal (menstrual-like) bleeding. No treatment is necessary, but if you are concerned, contact the doctor for advice.
If you forgot to take the medicine, take the missed tablet as soon as you remember. If more than 12 hours have passed since taking the last tablet, take the next dose without taking the forgotten dose. Do not take a double dose. Bleeding or spotting may occur if a dose is forgotten.
If you stop taking the medicine, do not stop treatment with the medicine without consulting the doctor. Adhere to the treatment regimen as recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, the use of Femoston-conti may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
The following diseases are reported more often in women taking hormone replacement therapy, compared to women not taking this therapy:
- Breast cancer
- Abnormal thickening or cancer of the uterine lining (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 treatment begins after age 65

For further information about these side effects, see section 2 "Before using the medicine".
Very common side effects (effects that may affect more than 1 in 10 users):
- Headache
- Abdominal pain
- Back pain
- Pain or tenderness in the breasts

Common side effects (effects that may affect up to 1 in 10 users):
- Vaginal thrush (a vaginal infection due to a fungus called Candida albicans)
- Depression, irritability
- Migraine. If you have a migraine-like headache for the first time, stop taking Femoston-conti and see a doctor immediately
- Dizziness
- Nausea, vomiting, bloating (abdominal swelling) including flatulence
- Allergic skin reactions [including rash, severe itching or hives (urticaria)]
- Menstrual irregularities such as irregular bleeding, spotting, painful periods, heavier bleeding or reduced bleeding
- Pelvic pain
- Vaginal discharge
- Generally feeling unwell, weakness or tiredness
- Swelling of the ankles, feet or fingers (peripheral edema)
- Weight gain

Uncommon side effects (effects that may affect up to 1 in 100 users):
- Cystitis-like symptoms
- Growing uterine masses (fibroids)
- Hypersensitivity reactions such as shortness of breath (allergic asthma)
- Change in sex drive
- Blood clots in the legs or lungs (venous thromboembolism or pulmonary embolism)
- Hypertension
- Circulatory problems (peripheral vascular disease)
- Enlarged and prominent veins (varicose veins)
- Indigestion
- Liver disorders, which may include yellowing of the skin (jaundice), weakness, generally feeling unwell and abdominal pain. If you notice yellowing of the skin or the whites of your eyes, stop taking Femoston-conti and contact the doctor immediately
- Gallbladder disease
- Swelling of the breasts
- Premenstrual syndrome
- Weight loss

Rare side effects (effects that may affect up to 1 in 1,000 users):
(*"Rare" frequency is attributed to side effects from post-marketing reports not observed in clinical trials)
- Illness resulting from the destruction of red blood cells (hemolytic anemia)*
- Meningioma (a brain tumor)*
- Change in the surface of the eye (deepening of corneal curvature)*, not being able to wear contact lenses (contact lens intolerance)*
- Heart attack
- Stroke*
- Swelling of the skin around the face and neck area. This may cause breathing difficulties (angioedema)
- Purplish spots (patches) on the skin
- Painful red skin nodules (erythema nodosum)*, discoloration of the skin, especially of the face or neck known as "pregnancy patches" (chloasma or melasma)*, leg cramps*

The following side effects have been observed in other types of hormone replacement therapies:
- Benign or malignant tumors, which may be affected by estrogen levels, such as endometrial cancer, ovarian cancer (see section 2 for further information)
- Increase in the size of tumors that may be affected by progestogen levels (such as meningioma)
- Immune system disease affecting many organs in the body (systemic lupus erythematosus)
- Probable dementia
- Exacerbation of seizures (epilepsy)
- Uncontrollable muscle spasms (chorea)
- Blood clots in the arteries (arterial thromboembolism)
- Inflammation of the pancreas (pancreatitis) in women with pre-existing high levels of certain blood lipids (high triglyceride levels in the blood)
- Rash with target-shaped red areas or sores (erythema multiforme)
- Urinary incontinence
- Painful/lumpy breasts (fibrocystic breasts)
- Cervical erosion
- Exacerbation of a rare blood pigment disorder (porphyria)
- High levels of certain blood lipids (hypertriglyceridemia)
- Increased total thyroid hormones

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you should consult with the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.
Storage conditions: Store in the original package, below 30°C.

6. FURTHER INFORMATION
In addition to the active ingredients, the medicine also contains:
- Each film-coated Femoston-conti 0.5 mg/2.5 mg tablet contains:
  Lactose Monohydrate, Maize Starch, Hypromellose, Colloidal Anhydrous Silica and Magnesium Stearate.
  The tablet film-coating contains:
  Polyvinyl Alcohol, Titanium Dioxide (E171), Macrogel 3350, Talc (E553b), Iron Oxide Yellow (E172).
  Each film-coated Femoston-conti 0.5 mg/2.5 mg tablet contains 117.4 mg lactose monohydrate.
- Each film-coated Femoston-conti 1 mg/5 mg tablet contains:
  Lactose Monohydrate, Maize Starch, Hypromellose, Colloidal Anhydrous Silica and Magnesium Stearate.
  The tablet film-coating contains:
  Hypromellose (HPMC 2910), Titanium Dioxide (E171), Macrogel 400, Iron Oxide Yellow (E172), Iron Oxide Red (E172).
  Each film-coated Femoston-conti 1 mg/5 mg tablet contains 114.7 mg lactose monohydrate.

What the medicine looks like and the contents of the package
Appearance:
Film-coated tablet containing an estradiol and dydrogesterone combination: Round, biconvex tablet, film-coated with a yellow (Femoston-conti 0.5 mg/2.5 mg) or salmon-colored (Femoston-conti 1 mg/5 mg) coating, on one side of which is imprinted the number '379'.
Packaging:
Each carton package contains: 28 or 84 (3 x 28) film-coated tablets packaged in a blister pack.
Not all package sizes may be marketed.
License holder and address: Abbott Medical Laboratories Ltd., Kiryat Atidim, P.O.B. 58099, Tel Aviv 61580.
Manufacturer's name and address: Abbott Healthcare Products B.V, Olst, the Netherlands.
Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:
Femoston-conti 0.5 mg/2.5 mg: 164-97-35630-00
Femoston-conti 1 mg/5 mg: 164-98-35631-00
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