PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only.

Duphaston

Film-Coated Tablets

Each tablet contains 10 milligram dydrogesterone
Inactive ingredients - see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicines. 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 is seems to you that their medical condition is similar.
The medicine is not intended for girls and adolescent girls below the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Dydrogesterone is a synthetic hormone very similar to the progesterone hormone produced by your body.
Duphaston is intended for treatment of conditions in which progesterone supplementation is necessary.

Therapeutic group: Progestogens.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see the list in section 6).
- you have a tumor or suspicion of a hormone-dependent tumor (estrogen and progesterone), such as a brain tumor called meningioma.
- unexplained vaginal bleeding has occured.
- you are being treated with a preparation that contains a combination of estrogen with progesterone.
- you are suffering from severe liver problems or have suffered in the past from liver function problems and your liver function values are still abnormal.

Do not use the medicine if one of the paragraphs above apply to you. If you are uncertain, refer to a doctor or pharmacist before use.

Special warnings regarding use of the medicine

If you are should take Duphaston because of unusual bleeding, the doctor must first clarify the reason for the bleeding before giving the medicine for treatment of this problem.

Before treatment with Duphaston, tell the doctor if:
one of the following conditions applies, has occurred in the past or worsened during pregnancy: porphyria (a rare hereditary blood disorder), depression, you are suffering from a rare hereditary problem of galactose intolerance, malabsorption of glucose or galactose, or Lapp-Lactase deficiency, you are sensitive to any food or medicine.

Unexpected spotting or vaginal bleeding may occur, primarily in the first months of treatment. Refer immediately to a doctor for consultation if the bleeding or spotting:
extends for more than a few months, occurs after you are already being treated for some time with the medicine, or continue also after completion of treatment with the medicine. Your doctor will clarify the reason for the bleeding or spotting and may ask you to have tests performed for detection of endometrial cancer.

Tell the doctor immediately if one of the following conditions occurs after the first use of the medicine or worsens:

- Severe unusual headache, migraine or symptoms that may indicate cerebral ischemia.
- Marked increase in blood pressure.
- Venous thrombosis or symptoms of venous thrombosis (painful swelling of the leg, sudden chest pain, shortness of breath).

When using sex hormones, monitoring is necessary if the following rare conditions develop or worsen during pregnancy: cholestatic icterus, herpes gestationis (an autoimmune skin disease) – a rare autoimmune skin disease that occurs during pregnancy and is characterized by blistering of the skin, severe pruritus, otosclerosis and porphyria.
Patients who suffered in the past from depression must be closely monitored. If severe depression develops again, stop treatment with dydrogesterone.

If you are taking, or have recently taken, other medicines including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking some of the following medicines. The medicines in the following groups may lower the effect of Duphaston, which may lead to a change in the bleeding pattern:

- Medicines to treat epilepsy – such as phenobarbital, carbamazepine, phenytoin, medicines to treat infections – such as rifampicin, rifabutin, nevirapine, efavirenz, medicines to treat HIV infection (AIDS) – such as ritonavir, nelfinavir and Hypericum-based herbal medicines (*Hypericum perforatum*, St. John's wort), valerian root, sage or ginkgo biloba.

Do not take with preparations containing a combination of estrogen and progesterone (see "Do not use the medicine if" section).

Girls and adolescent girls:
The efficacy and safety of Duphaston is unknown in adolescent girls aged 12-18, and therefore, is not intended for use in this age group.

Pregnancy and breastfeeding
Pregnancy: there may be an increased risk of hypospadias (a fracture at the bottom of the urethra, a congenital defect in the penis affecting the opening of the urethra) in children whose mothers took certain progestogens. However, this increased risk is still uncertain.
To date, there is no evidences that taking dydrogesterone during pregnancy is harmful. More than 9 million pregnant women have taken the medicine Duphaston.
If you are pregnant, consult with the doctor before using the medicine.
Breastfeeding: Do not take Duphaston if you are breastfeeding. It is not known whether Duphaston passes into breast milk and affects the baby. Studies on other progestogens show that small quantities of them pass into breast milk.

Driving and operating machinery
You may feel some drowsiness or dizziness after taking Duphaston, especially in the first few hours after administration. If this happens, do not drive or operate dangerous machinery. Check the effect the medicine has on you before driving and operating dangerous machinery.

Important information about some of the ingredients of the medicine
The medicine contains lactose.
If you suffer from a rare hereditary problem of galactose intolerance, malabsorption of glucose or galactose, or Lapp-Lactase deficiency, you must not take the medicine (see the beginning of the section).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the doctor only. **Do not exceed the recommended dosage**.

How to take the medicine:

- Do not chew/crush the tablet. Swallow each tablet with water. The tablets can be taken with or without food.
- If you have to take more than one tablet per day, distribute them evenly over the day. For example, take one tablet in the morning and one tablet in the evening.
- The tablet score line is only intended for splitting the tablet to make it easier to swallow. **Do not take a half a tablet only**.

Tests and Follow-up
Before commencing treatment with this medicine, the doctor will refer you for thorough medical tests. The tests will include: evaluation of family medical history and in addition, a gynecological and breast exam, in accordance with your medical history.

If you accidentally take a higher dose
If you took an overdose or if a child or anyone else has accidentally swallowed the medicine, the following signs may occur: nausea, vomiting, exhaustion and dizziness. Immediately proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine
If you forgot to take this medicine at the required time, take the next dose as soon as you remember. If more than 12 hours have passed from the time you were supposed to take the tablet, skip the forgotten dose and continue taking as usual from the next day. It is advisable to take the medicine every day at a set time. Do not take a double dose to compensate for a forgotten dose.
Adhere to the treatment regimen recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Duphaston may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment and contact the doctor immediately if you notice some of the following side effects:

- Painful swelling in the leg, sudden chest pain or difficulty breathing. These can be signs of a thromboembolism.
- Severe abnormal headache, migraine or symptoms that may indicate cerebral ischemia.
- A marked increase in blood pressure.
- Chest pain that radiates to the arm or neck. These can be signs of a heart attack.
- Dimples in the skin or breast; if you see or feel changes in the nipple or glands. These can be signs of breast cancer.
- Liver problems – signs can include yellowing of the skin or whites of the eyes (jaundice), feeling of weakness, general unwell feeling or abdominal pains (affect less than 1 in 100 patients).
- Allergic reactions – signs can include breathing difficulties or reactions that involve the whole body, such as nausea, vomiting, diarrhea or low blood pressure (affect less than 1 in 1,000 patients).
- Swelling of the skin around the face and neck that may cause breathing difficulties (affect less than 1 in 1,000 patients).

Common side effects – effects that occur in 1-10 in 100 users:
Migraine, headache, nausea, breast tenderness or pains, irregular, heavy or painful menstruation, amenorrhea or period that occurs at a lower frequency than normal, unexpected, heavy or painful bleeding.
Uncommon side effects - effects that occur in 1-10 in 1,000 users:
Weight gain, feeling dizzy, feeling depressed, vomiting, allergic reactions, allergic skin reactions - such as rash, severe pruritus or urticaria (an effect in which red, raised and itchy lesions appear), liver function problems accompanied by jaundice, weakness or tiredness, and abdominal pain.
Rare side effects – effects that occur in 1-10 in 10,000 users:
Somnolence, swelling of the breasts, hemolytic anemia – a kind of anemia that is caused when red blood cells are destroyed, edema and swelling due to accumulation of fluids, usually in the legs or ankles, an increase in the number of tumors affected by progestogens (such as meningioma), hypersensitivity of the immune system.

Side effects with combined use of Duphaston and estrogen:
Breast cancer, endometrial hyperplasia and cancer, ovarian cancer, venous thrombosis, myocardial infarction, cardiac disease, stroke.
If you are taking Duphaston together with estrogen, you must carefully read the warnings section in this leaflet and the information in the patient leaflet provided in the package of the estrogen containing medicine.

If one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, like any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: store in a dry place, at a temperature below 30°C.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Lactose monohydrate, maize starch, opadry Y-1-7000, methylhydroxypropylcellulose, colloidal anhydrous silica, magnesium stearate

Amount of lactose per tablet: 111.1 mg.
What the medicine looks like and the contents of the package – the package contains 20 round white tablets packaged in a blister. '155' is engraved on each tablet on both sides of the score line.
The score line is intended for easy splitting of the tablet so it will be easier to swallow the tablet. The score line is not intended for halving the dose into two equal doses.

- License holder and address: Abbott Medical Laboratories Ltd., Kiryat Atidim, P.O.B. 58099, Tel Aviv 61580.
- Manufacturer and address: Abbott Healthcare Products B.V., Weesp, The Netherlands.
- This leaflet was checked and approved by the Ministry of Health in: 07/2014.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 129-45-30880-00