

## **PATIENT INFORMATION**

### **AYGESTIN®**

**(norethindrone acetate tablets)**

Read this PATIENT INFORMATION before you start taking AYGESTIN® tablets and read what you get each time you refill AYGESTIN® tablets. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition.

### **What is the most important information I should know about AYGESTIN® (A Progestin Hormone) tablets?**

- **Do not use AYGESTIN® if you are pregnant, breast-feeding or are trying to conceive.**
- **Do not use AYGESTIN® if you have had a previous blood clot, stroke, or heart attack.**
- **Do not use AYGESTIN® if you are postmenopausal.**

### **What is AYGESTIN®?**

AYGESTIN® is similar to the progesterone hormones naturally produced by the body. Your healthcare provider may provide AYGESTIN® as individual tablets or in a blister pack of 10 tablets.

### **What are AYGESTIN® tablets used for?**

AYGESTIN® tablets are used for the treatment of secondary amenorrhea (absence of menstrual periods in women who have previously had a menstrual period who are not pregnant), the treatment of endometriosis, and the treatment of irregular menstrual periods due to hormone imbalance.

### **Who should not take AYGESTIN® tablets?**

**You should not take AYGESTIN® tablets if you are postmenopausal, pregnant or breast-feeding.**

You should not take AYGESTIN® tablets if you have the following conditions:

- **Known or suspected pregnancy.** AYGESTIN® tablets are not indicated during pregnancy as it may cause fetal harm when administered to pregnant women. There is an increased risk of minor birth defects in children whose mothers take AYGESTIN® during

the first 4 months of pregnancy (mild masculinization of the external genitalia of the female fetus, as well as hypospadias in the male fetus). If you take AYGESTIN<sup>®</sup> and later find out you were pregnant, talk with your healthcare provider right away

- **History of blood clots in the legs, lungs, eyes, brain, or elsewhere, or a past history of these conditions**
- **Liver impairment or disease**
- **Known or suspected cancer of the breast.** If you have or had cancer of the breast, talk with your healthcare provider about whether you should take AYGESTIN<sup>®</sup>
- **Undiagnosed vaginal bleeding**
- **Hypersensitivity to AYGESTIN<sup>®</sup> tablets.** See the end of this leaflet for a list of all of the ingredients in AYGESTIN<sup>®</sup>

### **What are the risks associated with AYGESTIN<sup>®</sup> tablets?**

- **Risk to the Fetus:**

AYGESTIN<sup>®</sup> tablets should not be used if you are pregnant. AYGESTIN<sup>®</sup> tablets are contraindicated during pregnancy as it may cause fetal harm when administered to pregnant women. There is an increased risk of minor birth defects in children whose mothers take this drug during the first 4 months of pregnancy. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and congenital abnormalities in male and female babies. Although it is not clear that these events were drug related, you should check with your healthcare provider about the risks to your unborn child of any medication taken during pregnancy.

You should avoid using AYGESTIN<sup>®</sup> tablets during pregnancy. If you take AYGESTIN<sup>®</sup> (norethindrone acetate tablets, USP) and later find you were pregnant when you took it, be sure to discuss this with your healthcare provider as soon as possible.

- **Abnormal Blood Clotting:**

Use of progestational drugs, such as AYGESTIN<sup>®</sup>, has been associated with changes in the blood-clotting system. These changes allow the blood to clot more easily, possibly allowing clots to form in the bloodstream. If blood clots do form in your bloodstream, they can cut off the blood supply to vital organs, causing serious problems. These problems may include a stroke (by cutting off blood to part of the brain), a heart attack (by cutting off blood to part of the heart), a pulmonary embolus (by cutting off blood to part of the lungs), visual loss or blindness (by cutting off blood vessels in the eye), or other problems. Any of these conditions may cause death or serious long-term disability. Call your healthcare provider right away if you suspect you have any of these conditions. He or she may advise you to stop using the drug.

- **Eye Abnormalities:**

Discontinue AYGESTIN<sup>®</sup> tablets and call your healthcare provider right away if you experience sudden partial or complete loss of vision, blurred vision, or sudden onset of bulging eyes, double vision, or migraine.

**These are some of the warning signs of serious side effects with progestin therapy:**

- Breast lumps
- Dizziness and faintness
- Changes in speech
- Severe headaches
- Chest pain
- Shortness of breath
- Pains in your legs
- Changes in vision

Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

**Common side effects include:**

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps/bloating
- Nausea and vomiting
- Hair loss

**Other side effects include:**

- High blood pressure
- Liver problems
- High blood sugar
- Fluid retention
- Enlargements of benign tumors of the uterus (“fibroids”)
- Vaginal yeast infections
- Mental depression

These are not all the possible side effects of progestin and/or estrogen therapy. For more information, ask your healthcare provider or pharmacist.

**What can I do to lower my chances of getting a serious side effect with AYGESTIN®?**

- Talk with your healthcare provider regularly about whether you should continue taking AYGESTIN®
- Have a breast exam and mammogram (breast x-ray) every year unless your healthcare provider tells you something else. If members of your family have had breast cancer or if you

have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often

- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease. Ask your healthcare provider for ways to lower your chances of getting heart attacks

### **General information about the safe and effective use of AYGESTIN® tablets**

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not take AYGESTIN® tablets for conditions for which it was not prescribed. Do not give AYGESTIN® tablets to other people, even if they have the same symptoms you have. It may harm them.

### **Keep AYGESTIN® tablets out of the reach of children.**

This leaflet provides a summary of the most important information about progestin and/or estrogen therapy. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about AYGESTIN® that is written for health professionals.

### **What are the ingredients in AYGESTIN® tablets?**

AYGESTIN® tablets contain the following inactive ingredients: lactose, magnesium stearate, and microcrystalline cellulose

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