

Description Jeanine ® tablets

Pharmacological Effects:

Jeanine - low-dose monophasic oral combined estrogen-progestin birth control pills.

The contraceptive effect Jeanine performed through three complementary mechanisms:

- Suppression of ovulation at the hypothalamic-pituitary regulation;
- Changes in the properties of cervical secretions, causing it to become impervious to sperm;
- Changes in the endometrium, which makes it impossible for the implantation of a fertilized egg.

In women taking combined oral contraceptives, menstrual cycle becomes more regular, less frequently observed in painful menstruation, decreases the amount of bleeding, resulting in reduced risk of iron deficiency anemia.

Pharmacokinetics

• dienogest

Absorption. After oral administration of dienogest is rapidly and completely absorbed, and its maximum concentration in blood serum equal to 52 ng / ml, reached after about 2.5 hours. Bioavailability of approximately 91-96%.

Distribution. Dienogest binds to albumin and blood serum does not bind to globulin, sex hormone binding (SHBG) and corticoid binding globulin (GLCs). In the free form is about 10% of the total concentration in blood serum, about 90% - are not specifically related to serum albumin. Induction of ethinylestradiol synthesis of SHBG does not affect the binding of dienogest with whey protein.

Metabolism. Dienogest is almost completely metabolized. Clearance from serum is about 3,4-3,7 l / h.

Excretion. The half-life is about 8,5-10,8 h. A small amount of unchanged form excreted in the urine as metabolites (T1 / 2 - 14.4 hours) are excreted in urine and bile in a ratio of about 3:1.

Equilibrium concentration. On the pharmacokinetics of dienogest does not affect the level of SHBG in serum. As a result, daily administration of the drug substance levels in serum increased approximately 1.5 times.

Ethinylestradiol

Absorption. After oral ethinylestradiol is rapidly and completely absorbed. The maximum concentration in serum, which is equal to about 67 pg / ml, achieved 1,5-4 hours. During the intake and the first passage through the liver ethinylestradiol is metabolized, resulting in its oral bioavailability is on average about 44%.

Distribution. Ethinyl estradiol almost completely (approximately 98%), although not specific, binds albumin. Ethinyl estradiol induces the synthesis of SHBG. The apparent volume of distribution of ethinyl estradiol is 2.8 - 8.6 L / kg.

Metabolism. Ethinylestradiol undergoes presystemic conjugation, as in the mucosa of the small intestine and the liver. The main pathway - aromatic hydroxylation. The rate of clearance from plasma is 2.3 - 7 ml / min / kg.

Excretion. Reduction of concentration of ethinyl estradiol in the blood serum is biphasic, the first phase is characterized by half-life of about 1 hour, the second - 10-20 hours. Unchanged from the body is not displayed. Ethinyl estradiol metabolites excreted in urine and bile in the ratio 4: 6 with a half-life of about 24 h.

Equilibrium concentration. Equilibrium concentration is achieved throughout the second half of the therapeutic cycle.

Indications:

Contraception.

How to use:

Dragees, taken orally in order specified on the package every day at about the same time, with a little water. Take one tablet daily continuously for 21 days. Reception begins next pack after the 7-day break in taking pills, during which usually occurs withdrawal bleeding. Bleeding usually starts 2-3 days after the last tablet and may not end before starting a new package.

How to start taking Jeanine

- If you do not receive any hormonal contraceptive in the previous month.

Receiving Janine begins on the first day of the menstrual cycle (ie the first day of menstrual bleeding). Allowed to start taking on 2-5 of the menstrual cycle, but in this case it is recommended to additionally use a barrier method of contraception during the first 7 days of pills from the first package.

- When switching from other COCs.

Preferably start accepting Janine the next day after taking the last active tablet from the previous packaging, but in

any case not later than the day after the usual 7-day break (for products containing 21drazhe) or after the last inactive tablet (for products containing 28 Pills in packaging).

- When switching from contraceptives containing only progestogens ("mini-pill, injectable form, the implant) or progestogen releasing intrauterine devices (Mirena).

A woman can go with the mini-pill on Jeanine any day (no break), with implants or intrauterine devices with progestogen - the day of his removal from the injection form - from the day would have to be made following injection. In all cases, you must additionally use a barrier method of contraception during the first 7 days of pills.

- After the abortion in the first trimester of pregnancy.

A woman can start taking the drug immediately. Subject to this condition, the woman needs no additional contraceptive protection.

- After childbirth or abortion in the second trimester of pregnancy.

We recommend you start taking the drug for 21-28 days after delivery or abortion in the second trimester of pregnancy. If the reception is started later, it is necessary to additionally use a barrier method of contraception during the first 7 days of pills. However, if a woman is already living a sexual life, prior to receiving Jeanine pregnancy must be excluded or must wait for the first menstruation.

Receiving missed pills

If the delay in receiving the drug was less than 12 hours, contraceptive protection is not reduced. Should take the pills as soon as possible, should be taken at the usual time.

If the delay in taking pills to more than 12 hours contraceptive protection may be reduced. Be guided by the following two basic rules:

- The drug should never be interrupted by more than 7 days.
- 7 days of continuous reception of pills required to achieve adequate suppression of the hypothalamic-pituitary-ovarian regulation.

Respectively, may be given the following advice, if the delay in taking pills to more than 12 hours (the interval from the date of reception of the last drops more than 36 hours):

- The first week of dosing

A woman should take the last missed tablet as soon as possible, as soon as you remember (even if it means taking two tablets at once). Next take the pills at the usual time. Must additionally be used a barrier method of contraception (eg condoms) for the next 7 days. If intercourse took place during the week before skipping pills, you must consider the likelihood of pregnancy.

The more pills missed, and the closer they are to break in the admission of active substances, the greater the chance of pregnancy.

- The second week of dosing

A woman should take the last missed tablet as soon as possible, as soon as you remember (even if it means taking two tablets at once). Next take the pills at the usual time.

Provided that the woman took tablets correctly in the 7 days preceding the first missed tablet, there is no need to use additional contraceptive measures. Otherwise, as well as skipping of two or more pills in addition to use barrier methods of contraception (eg condoms) for 7 days.

- The third week of dosing

The risk of reliability degradation is inevitable due to the upcoming break in the reception drops.

A woman must strictly adhere to one of the following two options. Moreover, if the 7 days preceding the first missed pills, all pills are taken correctly, there is no need to use additional contraceptive methods.

1. A woman should take the last missed tablet as soon as possible, as soon as you remember (even if it means taking two tablets at once). Next take the pills at the usual time, until the end drops from the current package. Next pack should be started immediately. Withdrawal bleeding is unlikely until the end the second pack, but may experience spotting and breakthrough bleeding while taking pills.

2. A woman may also interrupt the reception drops from the current package. Then it should take a break for 7 days, including day pass drops and then begin receiving a new package.

If a woman misses pills, and then during a break from taking pills she had no withdrawal bleeding, you need to

exclude pregnancy.

If a woman has had vomiting or diarrhea within 4 hours after taking the active pills, suction may not be complete and must be taken additional contraceptive measures. In these cases, should be guided by the recommendations while skipping pills.

In order to delay the onset of menstruation, women should continue taking pills from a new package Jeanine immediately after taken all the pills from the previous one, without a break in the reception. Sugar Plum out of this new package can be accepted as long as a woman wants (as long as the package is complete). In patients receiving the drug from the second pack of women may experience spotting or breakthrough uterine bleeding. Resume reception Jeanine from a new package follows the usual 7-day break.

In order to move the first day of menstruation on the day of the week, a woman should be advised to shorten the nearest break in the reception drops in as many days, how much she wants. The shorter the interval, the higher the risk that it will not have withdrawal bleeding, and in the future, will be spotting and breakthrough bleeding during the second pack (just as in the case when she wished to delay the onset of menstruation). In order to postpone the onset of menstruation, the woman should continue taking the drug, using the last 10 tablets from another pack Janine, without making a break in the reception. Thus, the cycle may be extended for up to 10 days until the end of the second pack. Against the background of the drug from the second Packing a woman may experience spotting or breakthrough uterine bleeding. Regular use of Jeanine and then resumed after the usual 7-day break in taking pills. In order to move the first day of menstruation on the day of the week, a woman should be reduced following a break in the reception drops to the desired number of days. The shorter the interval, the higher the risk that it will not have withdrawal bleeding in the future, will be spotting and breakthrough bleeding during the second pack (just as in the case when she wished to delay the onset of menstruation).

Side effects:

Soreness and tension of the mammary glands, breast enlargement, secretion from the mammary glands, spotting and breakthrough uterine bleeding, headache, migraine, changes in libido, decrease / mood changes, poor tolerance of contact lenses, visual disturbances, nausea, vomiting, pain abdomen; changes of vaginal secretion, skin rash, erythema nodosum, erythema multiforme, generalized pruritus, cholestatic jaundice, fluid retention, weight change, allergic reactions. Rarely - increased triglyceride levels of blood plasma, decreased carbohydrate tolerance, fatigue and diarrhea.

Sometimes it can develop chloasma, especially in women with a history of chloasma during pregnancy.

As with the admission of other COCs in rare cases may develop thrombosis and thromboembolism.

Contraindications:

Jeanine should not be applied if any of the states listed below. If any of these conditions develop for the first time while taking the drug should be immediately repealed.

- Thrombosis (venous and arterial) and venous thromboembolism in the present or in history (including deep vein thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular disorders).
- Conditions prior thrombosis (including transient ischemic attack, angina), now or in history.
- Migraine with focal neurological symptoms in history.
- Diabetes mellitus with vascular complications.
- Multiple or severe risk factors for venous or arterial thrombosis, including valvular heart lesions, cardiac arrhythmias, cerebrovascular disease or coronary heart uncontrolled hypertension.
- pancreatitis with severe hypertriglyceridemia, now or in history.
- Liver failure and severe liver disease (as long as liver tests do not come back to normal).
- liver tumors (benign or malignant), now or in history.
- Identification of hormone-dependent malignant disease (including the genitals or mammary glands) or suspicion on them.
- Vaginal bleeding of unknown origin.
- Pregnancy or suspicion of it.