Evelea

Levonorgestrel 0.150 mg
Ethinylestradiol 0.030 mg

Urufarma

LI-0000-01

Formula:
Each tablet contains Levonorgestrel 0.150 mg, Ethinylestradiol 0.030 mg and excipients (q.s.)

Therapeutic effect:
Contraceptive. This medicine regulates menstrual cycles.

Indications:
Preventing pregnancy. Regulation of menstrual cycles. Decrease and control dysmenorrhea.
Taking one daily tablet of **Evelea** inhibits ovulation, alters the cervical mucus, induces changes in the endometrium, and alters tubal motility, thus preventing pregnancy.

Posology and method of administration:
Take **Evelea** tablets (the "pill") according to these instructions, no more than 24 hours apart, to achieve the highest birth control efficacy.

Starting the treatment: Take the first pill of the pack orally on day 1 of the menstrual cycle - the day when menstrual bleeding starts. Then, take 1 pill per day, always at the same time, for 21 consecutive days. If you stop the treatment for 7 days, start a new pack on day 8. Start each new pack on the same day of the week when you took the first pill of the first pack.
Your will probably bleed during the seven-day break, generally on the day 3 or 4.
If you start taking this medicine exactly on day 1 of menstrual bleeding, no other birth control method needs to be added. If you do not start the treatment under these conditions, an additional birth control method should be used (barrier contraceptives such as condoms).

Continuing the treatment: You should start the following packs on the same day of the week as the first pill of the first pack, using the same dosage regime: 21 days of treatment, followed by a 7-day break.
If for any reason you do not start the next packs on the right day, an additional birth control method must be used (barrier contraceptives, such as condoms), for at least 10 days.
When all 21 tablets are taken correctly, birth control protection lasts the whole month, including the 7-day break.

What to do if you miss a pill: Missing a pill may expose you to getting pregnant.
If you miss a pill, take it as soon as you remember. You realise you missed a dose within 12 hours of the regular time, take it immediately, and continue the treatment as usual.
If more than 12 hours have passed, the efficacy decreases. In this case, take the missed pill as soon as you remember and continue the treatment. This means you may take two pills on the same day. In this case, you must use an additional birth control method (barrier contraceptive), such as condoms, during the following 7 to 10 days.
If you missed more than one pill, continue taking the following pills, and you must use a condom until you start a new pack.
If you do not bleed after finishing 21 days of treatment, especially if you followed the treatment correctly, you need to make sure you are not pregnant before starting a new pack.

Stopping the treatment: If you decide to stop the treatment, finish taking this pack and do not restart the treatment with a new pack.
The next cycle may last a few more days than the previous ones.
From this month onwards, your ability to bear children is restored.
Available statistical data suggest it is best to wait until the third month without treatment before attempting to get pregnant, due to the possibility of twin pregnancy.

Warnings:
Vomiting or diarrhoea episodes may reduce the contraceptive efficacy. An additional non-hormonal barrier method, such as a condom, should be used.
Women taking oral contraceptives should be advised to quit smoking because of the increased risk of cardiovascular adverse events.
The use of oral contraceptives is associated with an increase in certain diseases such as myocardial infarction, stroke, thromboembolism, deep vein thrombosis, liver neoplasms, gall bladder disease, and hypertension. Use of these preparations in patients with hypertension, hypercholesterolaemia, hypertriglyceridaemia, smokers, diabetics, obese women, and women over 35 years of age, especially if they have any cardiovascular risk factors, should be avoided, as the risk of serious (cardiovascular) events would be significantly increased.
Tell your doctor if you have recently given birth, had an abortion or stopped breastfeeding, or if you have any medical condition. The use of oral contraceptives is associated with decreased breast milk production, if given immediately after delivery.
Discontinue the treatment in the event of previously unknown severe headaches or migraine, unusual pain and oedema in the lower limbs, cough, or difficulty in breathing, and tell your doctor as soon as possible.
The use of combined contraceptives is associated with an increased risk of developing venous thromboembolism (VTE). However, venous thromboembolism can occur whether or not you take the contraceptive, and it can also occur if you get pregnant. The risk of developing VTE is higher in users of birth control pills than in non-users, but not as high as the risk of developing VTE during pregnancy.
Hormonal contraceptives do not protect against HIV infection (AIDS) or any other sexually transmitted diseases.

Precautions:
Patients with lipid metabolism disorders, hypercholesterolemia and hypertriglyceridaemia should be checked periodically if they choose to be treated with oral contraceptives. Progestogens can raise LDL levels and make hypercholesterolemia more difficult to control. If the patient develops jaundice, the medication should be stopped, and the patient studied to discover the cause. If patients develop symptoms of depression while taking oral contraceptives, this medication should be discontinued, and an alternative method of contraception should be used in order to determine if the depression is drug-related. Patients who wear contact lens who develop visual changes while taking contraceptive medication or intolerance to contact lenses should be evaluated by an ophthalmologist.

Contraindications:
Hypersensitivity to any of the components.
Evelea should not be administered in case of pregnancy, whether confirmed or suspected, liver disease, diabetes, arterial or venous disease. This medicine is contraindicated in patients with breast cancer, whether known or suspected, or any other oestrogen-dependent malignancy.
Evelea is contraindicated in patients with kidney, liver, or adrenal failure.

Drug-drug interactions:
Medicines that function as competitive sulphation inhibitors in the gastrointestinal tract, such as ascorbic acid, may increase the bioavailability of ethinylestradiol.
Concomitant use with enzyme inducers (rifampicin, phenylbutazone, phenytoin, griseofulvin) and antibiotics (e.g., ampicillin, amoxicillin) may decrease contraceptive efficacy.
The use of oral contraceptives may affect the efficacy of the following medicines: cyclosporine, theophylline, diazepam, and probably other benzodiazepines and tricyclic antidepressants.

Side effects:
Headaches, stomach aches, nausea, breast tension, depressive mood or changes in body weight may occur infrequently and exceptionally. In susceptible patients, prolonged treatments may cause facial pigmentation to appear, which may increase with sun exposure.

Presentation:
Calendar pack containing 21 tablets.
Keep at room temperature (15 - 30°C).
In case of poisoning, seek medical assistance immediately.
Keep out of the reach of children.

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