Femexin 28

Levonorgestrel 0.100 mg
Ethinylestradiol 0.020 mg

Urufarma

LI-0000-00

Formula:
Each white coated tablet contains: Levonorgestrel 0.100 mg, ethinylestradiol 0.020 mg, and excipients (q.s.)
Each red tablet (dummy medication) contains excipients (q.s.)

Therapeutic effect:
Contraceptive.

Indications:
Preventing pregnancy.

Mode of action:
Oral contraceptives act by gonadotrophin suppression. Although the main mechanism is the inhibition of ovulation, there are pharmacological actions that include changes in the cervical mucus and endometrium, which hinder the flow of sperm cells through the cervix and the implantation of the fertilised egg in the uterus.

Posology and method of administration:
Take **Femexin 28** tablets ("the pill" for short) strictly according to these instructions, no more than 28 hours apart, to achieve the highest contraceptive efficacy.
Take 1 pill of **Femexin 28** per day, preferably by night, without interruption for 28 days (1 white pill every day for the first 21 days and one red pill for the remaining 7 days), without taking a break between 2 packs.
Start the treatment with the white pill located in the position marked as No. 1 (you must take the first white pill on the first day of menstruation corresponding to the first bleeding), and continue taking one white pill per day, following the numeric order, so that the last 7 pills of the cycle always correspond to the 7 red pills.
Menstruation with occur while taking the 7 red pills. If you wish to continue the treatment, the day after taking the last red pill, start a new pack and take the first white pill.
It is of the utmost importance to follow the order, taking the white pills first and once you have finished them, start taking the red pills. According to this proposed regime, you will take pills every day without rest, for as long as you wish to avoid getting pregnant.
If you start treatment with **Femexin 28** and change from another oral contraceptive, you must take the first white pill after a 7-day break from the previous oral contraceptive if it had 21 pills or start taking this medicine without a break if the previous pack had 28 pills. If you do not have your menstrual bleeding during the 6 or 7 days after finishing the previous contraceptive pack, talk to your doctor to rule out pregnancy, before starting treatment with **Femexin 28.**
What to do if you miss a pill: Missing an active pill (white) may expose you to getting pregnant. If you realise you have missed a dose within 12 hours of the usual time, take the pill that you missed immediately and continue the treatment as usual taking the following pill of that day at the usual time. If you realize you have missed a dose and more than 12 hours have passed from the usual time, you may risk getting pregnant. In this case: take the pill that you missed immediately.
Continue the treatment until you finish the pack. Simultaneously, use a non-hormonal birth control method (barrier contraceptive: condom) until you start a new pack, including the time when you might experience menstrual bleeding.
Once you stop taking **Femexin 28,** your ability to bear children is restored. The first cycle without treatment may last one week more than usual, but further cycles will go back to normal.
It is best to wait until the third month without treatment before attempting to get pregnant, due to the possibility of twin pregnancy.

Contraindications:
Hypersensitivity to any of the components of the formula.
Femexin 28 should not be used in case of pregnancy, liver disease, diabetes, arterial or venous disease, vaginal bleeding of undiagnosed cause, amenorrhoea of unknown cause, known or suspected breast cancer or other oestrogen-dependent malignancy.
Combined oral contraceptives (COCs) should not be used in case of any of the following conditions: Presence or risk venous thromboembolism (VTE)
- Venous thromboembolism: current VTE (with anticoagulants) or history of VTE (e.g., deep vein thrombosis (DVT) or pulmonary embolism (PE)).
- Known hereditary or acquired predisposition to venous thromboembolism, such as activated protein C (APC) resistance (including factor V Leiden), antithrombin III deficiency, protein C deficiency, protein deficiency.
- Major surgery with prolonged immobilisation.
- Increased risk of venous thromboembolism due to the presence of a number of risk factors.

Presence or risk of arterial thromboembolism (ATE).
- Arterial thromboembolism current arterial thromboembolism, history of arterial thromboembolism (e.g., myocardial infarction) or prodromal condition (e.g., angina pectoris).
- Cerebrovascular disease: current stroke, history of stroke, or prodromal condition (e.g., transient ischaemic attack, TIA).
- Known hereditary or acquired predisposition to arterial thromboembolism, such as hyperhomocysteinemia and antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).
- History of migraine with focal neurological symptoms.
- Elevated risk of arterial thromboembolism due to multiple risk factors or the presence of a severe risk factor such as diabetes mellitus with vascular symptoms, severe hypertension, or severe dyslipoproteinaemia.

Precautions and warnings:
The occurrence of vomiting or diarrhoea may reduce contraceptive efficacy of **Femexin 28**, in which case you should use another additional non-hormonal birth control method (barrier contraceptive, such as a condom).
Women taking oral contraceptives should be advised to quit smoking because of the increased risk of cardiovascular adverse effects.
Oral contraceptive use is associated with an increase in certain diseases such as myocardial infarction, stroke, thromboembolism, deep vein thrombosis, liver neoplasms, gallbladder disease, and hypertension.
The risk is low in healthy women with no other associated risk factors.
In patients with hypertension, hypercholesterolaemia, hypertriglyceridaemia, smokers, diabetics, obese women, and women over 35 years of age, especially if they have a cardiovascular risk factor, use these preparations should be avoided, as the risk of serious events would be significantly increased.
Talk to 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 has been associated with a decrease in breast milk production if given immediately after birth.
Discontinue 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 contraceptive users 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 disease.
Patients with lipid metabolism disorders, hypercholesterolaemia, or 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 discontinued, and the patient studied to discover the cause of the symptom. If patients develop symptoms of depression while taking oral contraceptives, the medication should be discontinued, and an alternative method of contraception should be used 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.
The dummy tablets of this medicine contain lactose. Patients with hereditary intolerance to galactose, Lapp lactase insufficiency, or malabsorption of glucose or galactose should not take this medicine.

Drug-drug interactions:
Drugs that function as competitive sulphation inhibitors in the gastrointestinal tract, such as ascorbic acid, may increase the bioavailability of ethinylestradiol. Ampicillin and tetracycline may decrease the enterohepatic circulation of ethinylestradiol by reducing plasma concentrations. Medicines that increase gastrointestinal motility, such as metoclopramide, reduce the absorption of hormones.
Medicines that induce hepatic microsomal enzymes such as rifampicin, barbiturates, phenylbutazone, phenytoin, griseofulvin, primidone, carbamazepine, and possibly also topiramate, felbamate, and oxcarbazepine may decrease ethinylestradiol concentrations. Herbal medicines containing hypericum (St. John's Wort) should not be taken because contraceptive efficacy may be lost. The enzyme-inducing effect of hypericum may persist for at least 2 weeks after discontinuation of administration. Concomitant use of rifampicin has been associated with decreased efficacy of oral contraceptives. Ethinylestradiol may interfere with the hepatic metabolism of other medicines such as cyclosporine or theophylline, either by inhibiting hepatic microsomal enzymes or by affecting glucuronidation.
HIV protease inhibitors (e.g., ritonavir) and non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine), and combinations thereof, have also been reported to potentially increase hepatic metabolism.
Women being treated with any of these drugs should temporarily use a barrier method or another method of contraception in addition to the COC. If you take liver enzyme inducing medicines, you should use the barrier method throughout concomitant treatment and for the following 28 days after discontinuation. If you continue the treatment after finishing the pills in the COC pack, you should start the next pack of COCs immediately after the previous one.
Troleandomycin may increase the risk of intrahepatic cholestasis during coadministration with COCs.
COCs induce the metabolism of lamotrigine, so that plasma concentrations of this medicine will be sub-therapeutic.

Adverse reactions:
Headaches, stomachache, nausea, abdominal pain, breast tension, depressive episodes, mood disturbances, breast pain, breast tenderness, or changes in body weight may occur in rare occasions. Prolonged treatments may cause facial pigmentation to appear in susceptible patients, which may increase with sun exposure.
Serious adverse reactions are arterial and venous thromboembolism. Very rarely, the following have been reported: fluid retention, migraine, decreased libido, vomiting, diarrhoea, rash, urticaria, and breast enlargement.

Presentation:
Packs containing 21 white tablets and 7 red 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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