

Femexin

Coated tablets

Formula:

Each tablet contains 0,100 mg Levonorgestrel, 0,020 mg Ethinyl Estradiol, Manitol and other excipients q.s.

Therapeutic action:

Contraception. Regulates the menstrual cycles.

Indications:

Prevention of pregnancy, regulation of the menstrual cycles and reduction and control of dysmenorrhea.

One daily tablet of **Gesibelle** inhibits ovulation, changes the cervical mucus, causes changes in the endometrium and disrupts tubal motility, all these mechanisms result in the prevention of pregnancy.

Dosage and method of administration:

To achieve maximum contraceptive efficacy, **Gesibelle** has to be taken as prescribed at intervals not exceeding 24 hours.

To start treatment:

Start by taking the 1st tablet in the pack orally on the first day of your menstrual cycle, i.e., the 1st day of the menstrual bleeding. Then take 1 tablet per day, always at the same time of the day for 21 days in a row. The therapy is then interrupted for 7 days, to be resumed on the 8th day starting with a new package. Each pack is started on the same day of the week you took the first tablet of the first pack.

Bleeding should occur within the 7-day break, usually on the 3rd or 4th day.

If you started taking the tablet exactly on the first day of the menstrual bleeding there is no need to add any other contraceptive methods. Otherwise, an additional contraceptive method (barrier: condom) should be added.

Continuation of treatment:

Subsequent packages should be started on the same day of the week you took the first tablet of the first pack, following the same scheme: taking 21 tablets and then resting for 7 days.

If, for any reason the subsequent packages are not started on the appropriate day, an additional backup method (barrier: condom) should be used at least for 10 days.

If the 21 tablets are taken correctly, the contraceptive protection will be maintained throughout the month, including the resting week.

Missed tablet:

Failing to take a tablet may result in pregnancy.

Whenever you forget to take a tablet, you should take it as soon as you realize it. If you notice you missed a tablet within 12 hours of the usual time, take it right away and proceed with treatment as usual.

If more than 12 hours have already gone by, the effectiveness of the drug is reduced. In such case, the missed tablet should be taken as soon as you remember it, and you should resume treatment, even if you have to take 2 tablets the same day. In that case, make sure you use an additional barrier method like condoms for the following 7 to 10 days. If you forget more than 1 tablet, continue taking the rest of the package and make sure you use condoms until you start your new pack.

If bleeding fails to occur after you have completed the 21 days of treatment, especially if treatment was followed correctly, you must rule out pregnancy before starting a new pack.

Discontinuation of treatment:

If you decide to discontinue treatment, finish the package and do not restart treatment with a new one.

The cycle that follows may last a few days longer than the previous ones.

From this month on you will recover your child-bearing potential.

The statistical evidence available suggests it is better to wait until the third month without treatment before seeking pregnancy, to reduce the likelihood of twin pregnancies.

Warnings:

Episodes of vomiting or diarrhea may reduce the efficacy of contraception. It is recommended to use an additional non-hormone method, e.g. condom (barrier method).

Women taking oral contraceptives should be advised to quit smoking cigarettes, since there is evidence showing they have a higher risk of presenting cardiovascular adverse events.

The use of oral contraceptives is associated with an increased frequency of certain conditions, such as myocardial infarction, stroke, thromboembolism, deep vein thrombosis, liver malignancies, gall bladder disease and hypertension.

In patients with hypertension, hypercholesterolemia, hypertriglyceridemia, smokers, diabetes, obese women and women over 35 years of age, especially if they have any cardiovascular risk factors, it would be advisable to avoid these formulations, because the risk of serious events (cardiovascular) would be significantly increased in those populations.

It is advisable to discuss it with your doctor if you recently had a baby, an abortion or stopped breastfeeding, or if you suffer from any ailment. The use of oral contraceptives is associated with a reduced lactation, when administered immediately after childbirth.

Treatment should be discontinued and you should consult your doctor promptly if you start having migraines, intense headaches of new onset, or unusual leg pain and edema, cough or respiratory distress.

Precautions:

Patients with lipid metabolism disorders, hypercholesterolemia and hypertriglyceridemia who choose to take oral contraceptives should be monitored regularly. Progestins may raise serum LDL levels and may render high serum cholesterol levels more difficult to keep under control. If the patient develops jaundice, medication must be discontinued and the patient should undergo a work-up to find the underlying cause. Medication should be discontinued if the patient develops symptoms of depression while taking oral contraceptives, and an alternative method of contraception must be used, to determine whether depression is drug-related. Patients who wear contact lenses and develop visual changes while on contraceptive medication, or who present intolerance to contact lenses for the first time, should be evaluated by an ophthalmologist.

Contraindications:

Hypersensitivity to any component.

Gesibelle cannot be administered in the presence of confirmed or suspected pregnancy, liver disease, diabetes, or arterial or venous disease. It is contraindicated in the presence of known or suspected breast cancer, or some other estrogen-dependent malignancy.

Gesibelle is contraindicated in patients with renal, liver or adrenal failure.

Drug Interactions:

Drugs that act as competitive inhibitors of sulfation in the gastrointestinal tract, such as ascorbic acid, may increase the bioavailability of Ethinyl Estradiol.

The simultaneous use of enzyme inducers (Rifampin, Phenylbutazone, Phenytoin, Griseofulvin), antibiotics (e.g., Ampicillin, Amoxicillin) may reduce the efficacy of contraception.

The use of oral contraceptives may affect the efficacy of the following drugs: Cyclosporine, Theophylline, Diazepam, and possibly other benzodiazepines and tricyclic antidepressants.

Side effects:

Patients may experience rare and isolated headaches, stomach aches, nausea, breast tenderness, depressive states or body weight changes. In susceptible patients, prolonged treatment can cause the appearance of facial pigmentation, which may increase with the exposure to sun.

Presentation:

Calendar pack containing 21 tablets.

Storage:

Store at room temperature, preferably below 30°C.

Keep out of the reach of children.