

# Divina 21

Coated tablets

## Formula:

Each coated tablet contains 3.00 mg Drospirenone, 0.030 mg Ethinyl Estradiol 0.030 mg and excipients q.s.

## Therapeutic action:

Contraception. Regulates the menstrual cycles.

## Directions:

This drug is used to prevent pregnancy. Regulate menstrual cycles.

Reduce and control dysmenorrhea.

Taking one tablet of **Maxinelle** a day inhibits ovulation, changes the cervix mucus, it causes changes in the endometrium and alters tubal motility; all these mechanisms prevent pregnancy.

## Dosage and method of administration:

To achieve maximum contraceptive effectiveness **Maxinelle** should be taken as instructed above, at intervals not exceeding 24 hours.

## To start treatment:

The first day of the menstrual cycle, that is the day the menstrual bleeding starts, take the first tablet of the package orally. Then take one tablet per day, always at the same time for 21 consecutive days. Treatment is interrupted for 7 days, and on the 8<sup>th</sup> day you should start a new package. Each package should be started on the same day of the week as the first tablet of the first pack. Bleeding occurs during the 7-day break, usually on the 3<sup>rd</sup> or 4<sup>th</sup> day.

If you started taking the tablet exactly on the first day of the menstrual bleeding, you do not need to add any other contraceptive method (barrier: condom).

## Continuation of treatment:

The following packages should be started on the same day of the week as the first tablet of the first pack, with the same scheme: take every day for 21 days, and then leave 7 days off. If, for any reason the following pack is not started the appropriate day, make sure you use an additional backup method (barrier: condom) at least for 10 days. When the 21 tablets are taken properly the contraceptive protection will be maintained throughout the month, including the week off therapy.

## Missed tablet:

If you forget to take a tablet there are chances that you may get pregnant. If you miss one tablet you should take it as soon as you can.

If you notice you missed a tablet within 12 hours of the time you should have taken it, take it immediately and continue with treatment as usual. If more than 12 hours have already gone by the effectiveness of the drug decreases. In this case the missed tablet should be taken when you remember about it, and continue with treatment even if you have to take 2 tablets on the same day. In this case you should use an additional barrier method like condoms for the next 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 a new pack.

If there is no bleeding after you have completed 21 days of treatment, especially if treatment had not been 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 next cycle may persist several days longer than previous ones. From this month on you will recover your child-bearing potential. There is statistical evidence that suggests you should wait until the third month without treatment before you seek pregnancy, to reduce the likelihood of twin pregnancies.

## Warnings:

Episodes of vomiting or diarrhea may reduce the drug's contraceptive efficacy. It is recommended to use an additional non hormone method such as a barrier method, as condom.

Women taking oral contraceptives should be advised to quit smoking cigarettes, given the evidence of an increased risk of 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.

These formulations would not be recommended in patients with hypertension, hypercholesterolemia, hypertriglyceridemia and diabetes, in smokers and/or obese women, or in women over 35 years old, especially if they have any cardiovascular risk factors, because their risk of presenting serious (cardiovascular) events would be significantly increased.

Patients treated with drugs with the potential of raising serum potassium levels (ACE inhibitors, angiotensin II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, NSAIDs) should get their serum potassium levels checked during the first course of treatment.

If you recently had a baby, an abortion, a miscarriage, or if you just stopped breastfeeding or suffer from any disease it is advisable to ask your doctor before you start taking the tablets. The use of oral contraceptives is associated with decreased production of breast milk if given immediately after childbirth.

You should discontinue treatment right away and see your doctor if you start suffering migraines or severe headaches unknown until then, unusual pain and edema in the lower limbs, cough or difficulty breathing.

**Precautions:**

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

**Contraindications:**

Hypersensitivity to any component of the drug.

**Maxinelle** should not be administered if pregnancy has been confirmed or is suspected, if the patient has liver disease, diabetes, or arterial or venous disease.

It is contraindicated in the presence of known or suspected breast cancer, or any estrogen-dependent malignancy.

**Maxinelle** 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.

There is a potential risk of increased serum potassium levels in women taking Drospirenone together with drugs that increase the serum potassium concentrations (ACE inhibitors, angiotensin II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, NSAIDs).

The use of oral contraceptives may affect the effectiveness of the medicines below.

Cyclosporine, Theophylline, Diazepam, and probably 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 sun exposure.

**Presentation:**

Calendar pack containing 21 coated tablets.

**Storage:**

Store at room temperature, preferably below 30°C.

Keep out of the reach of children.