# *Diva*

Drospirenone 3.00 mg
Ethinyl Estradiol 0.02 mg

**Formula:**
Each white-coated tablet contains: 3.00 mg Drospirenone, 0.02 mg Ethinyl Estradiol and excipients q.s.
Each red-coated tablet contains: Excipients q.s.

**Therapeutic action:**
Contraceptive. Regulator of menstrual cycles.

**Indications:**
Prevention of conception. Regulation of menstrual cycle. Reduction and control of dysmenorrhea.
Taking one tablet of ***Diva*** a day inhibits ovulation, modifies cervical mucus, causes endometrial changes and alters tubal motility, thus preventing pregnancy.

**Dosage and method of administration:**
For maximum contraceptive effectiveness ***Diva*** must be taken fully in accordance with these instructions and at intervals of no more than 24 hours.

**To start the treatment:**
Take by mouth the first tablet contained in the blister pack on Day 1 of the menstrual cycle, that is, the first day of menstrual bleeding. Take one tablet daily for 28 consecutive days, always at the same time of day. Take all 24 white tablets first, followed by the 4 red tablets. Always start each blister pack on the same day of the week as the first tablet of the first blister pack was taken.
Bleeding will occur during the period of administration of the red tablets.
If the tablets were started precisely on the first day of menstrual bleeding, no other contraceptive method needs to be used. If the treatment was not started as described above, an additional barrier method (condom or diaphragm) must be used.
**Continuation of treatment:** Subsequent blister packs must be started on the same day of the week as the first tablet of the first blister pack was taken, following the same regimen: 24 white tablets followed by 4 red tablets. If for any reason subsequent blister packs are not started as described above, an additional, barrier contraceptive method (condom or diaphragm) must be used for at least 10 consecutive days. Contraceptive protection is maintained over the whole month, including the period of administration of the red tablets.
**Forgotten or missed tablets:** If a tablet is not taken at the usual time, it must be taken as soon as remembered.
If the forgotten tablet is remembered within 12 hours of the usual time, it must be taken immediately and the treatment continued as usual.
Effectiveness is reduced if the forgotten tablet is remembered more than 12 hours after the usual time. The tablet must be taken as soon as remembered, and the treatment continued even if it means taking 2 tablets on the same day.
In this case, an additional barrier contraceptive method (condom or diaphragm) must be used for the next 7 to 10 days. If more than 1 tablet is missed, take the remainder of the tablets in the blister pack as usual, and use an additional barrier contraceptive method until a new pack is started.
If bleeding does not occur after 28 days of treatment, especially if these instructions have not been followed correctly, take a pregnancy test to ensure that conception has not occurred before starting a new blister pack.
**Stopping treatment:** To interrupt the treatment, finish taking all remaining tablets in the blister pack and do not start a new one. The next menstrual cycle may be a few days longer than previous cycles. Fertility will be restored as from that month. Statistical studies suggest waiting 3 months after discontinuing the treatment before attempting to conceive, because of the higher chances of conceiving twins if conception occurs earlier.

**Warnings:**
Episodes of vomiting or diarrhea may reduce contraceptive effectiveness. An additional, non-hormonal, barrier contraceptive method (e.g. condom) is recommended.
Women taking oral contraceptives are advised to stop smoking because of the risk of adverse cardiovascular events. Use of oral contraceptives is associated with higher incidence of certain illnesses, such as myocardial infarction, cerebrovascular accident, thromboembolism, deep vein thrombosis, hepatic neoplasias, gall bladder disease and hypertension.
Patients with hypertension, hypercholesterolemia or hypertriglyceridemia, and those who smoke, are diabetic, obese, or over 35 years old, especially those having cardiovascular risk factors, are advised not to use oral contraceptives due to the significant increase in the risk of serious (cardiovascular) events. Patients undergoing treatment with drugs that may increase serum potassium (ACEIs, Angiotensin II antagonists, potassium-sparing diuretics, Heparin, Aldosterone antagonists, NSAIs) must have their serum potassium levels tested during the first treatment cycle.
Patients who have recently given birth, had an abortion or stopped breast-feeding or are suffering from any illness are advised to consult a physician.

Oral contraceptive use is associated with diminished breast milk production, if the tablets are taken immediately after childbirth.
Patients who have migraines or severe headaches not previously experienced, unusual pain and edema of the lower limbs, coughing or respiratory difficulty, must discontinue the treatment and consult a physician without delay.
Use of combined contraceptives is associated with increased risk of developing venous thromboembolism (VTE). However, VTE may also occur in patients who do not take contraceptives or are pregnant. Although the risk of VTE is higher in contraceptive users than in non-users, it is highest during pregnancy. Hormonal contraceptives do not provide protection against infection with HIV (AIDS) or other sexually transmitted diseases.

**Precautions:**
Patients with lipid metabolism disorders, hypercholesterolemia or hypertriglyceridemia should be monitored regularly if they choose to take oral contraceptives. Progestogens can elevate LDL levels and make hypercholesterolemia more difficult to control. If the patient develops jaundice, the medication must be discontinued and investigations carried out to determine its cause. Patients who develop symptoms of depression while taking oral contraceptives, must discontinue the treatment and use an alternative contraceptive method to determine whether the depression is associated with the medication. Patients who wear contact lenses and who experience visual changes while taking contraceptive medication or who develop intolerance to contact lenses must consult an ophthalmologist.

**Contraindications:**
Hypersensitivity to any of the ingredients.
***Diva*** must not be administered to patients who are or might be pregnant or who suffer from liver disease, diabetes, or arterial or venous disease.
It is contraindicated in the presence of known or suspected breast cancer or other estrogen-dependent neoplasia.
***Diva*** is contraindicated in patients with renal, hepatic or adrenal insufficiency.

**Drug interactions:**
Drugs that act as competitive inhibitors of sulphation in the gastrointestinal tract, such as ascorbic acid, can increase the bioavailability of Ethinyl estradiol.
Concomitant use of enzyme inducers (Rifampicin, Phenylbutazone, Phenytoin, Griseofulvin) or antibiotics (e.g. Ampicillin, Amoxicillin), may diminish contraceptive efficacy.
Patients concomitantly undergoing treatment with Drospirenone and drugs that increase serum potassium (ACEIs, Angiotensin II antagonists, potassium-sparing diuretics, Heparin, Aldosterone antagonists, NSAIs) are potentially at risk for increased serum potassium.
Oral contraceptive use may affect the efficacy of the following drugs: Cidosporin, Theophylline, Diazepam, and probably other benzodiazepines and tricyclic antidepressants.

**Side effects:**
Some patients may occasionally experience headaches, stomach-aches, nausea, breast tenderness, depressive states or changes in body weight. In susceptible patients, long-term treatment can produce facial pigmentation, which may be exacerbated by exposure to the sun.

**Presentation:**
Blister pack containing 24 white-coated tablets and 4 red-coated tablets.
Store at room temperature (15-30°C).
Keep out of the reach of children.