CONTRACEPTIVES
Urufarma

Diva Continuo

Drospirenone 3.00 mg
Ethinylestradiol 0.02 mg

Formula:
Each tablet contains: Drospirenone 3.00 mg, ethinylestradiol 0.02 mg, and excipients (q.s.)

Therapeutic effect:
Contraceptive.

Indications:
Preventing pregnancy.
Taking one daily tablet of **Diva continuo** inhibits ovulation, alters the cervical mucus, induces changes in the endometrium, and alters tubal motility, thus preventing pregnancy.

Posology and method of administration:
Take **Diva continuo** tablets ("the pill" for short) strictly according to these instructions, no more than 24 hours apart, to achieve the highest contraceptive efficacy. Do not take this medicine for more than 120 days.
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 28 consecutive days. If you start taking this medicine exactly on day 1 of menstrual bleeding, no other contraceptive method needs to be added. If you do not start the treatment under these conditions, an additional method should be used (barrier contraceptives: condoms).
Continuing the treatment: Start the packs of the same day as the first pill of the first pack, and always on the day after finishing the previous pack. If for any reason you do not start the next packs on the right day, an additional method must be used (barrier contraceptives: condoms), for at least 10 days.
After taking 28 consecutive pills (1 pack), you may choose to have a 4-day break and start taking the second pack on day 5. If you choose to not take a break, you may start taking the second pack. You may only choose to take a break after finishing a whole pack (28 pills).
Every time you take a 28-pill pack, you may choose to have a 4-day break or go on to taking another pack with no breaks.
Birth control protection lasts the whole month, including the 4-day break. Continuous treatment should not last over 4 months. If you have not taken a break after 4 months, you must take the 4-day break at that point before starting any further packs.
What to do if you miss a pill: 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 skipped 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.
Stopping the treatment: If you decide to stop the treatment, finish taking this pack and do not restart the treatment with a new pack. 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. In patients receiving treatment with drugs that can increase serum potassium (ACE inhibitors, angiotensin II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, NSAIDs), serum potassium levels should be checked during the first cycle of treatment.
Women with hypertriglyceridemia or a family history of hypertriglyceridemia may be at increased risk of pancreatitis when using combined oral contraceptives (COCs).
In patients with hereditary angioedema, exogenous oestrogens may induce or exacerbate angioedema symptoms. Tell your doctor if you have recently given birth, had an abortion or miscarriage, 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 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 diseases.

Precautions:
Patients with lipid metabolism disorders, hypercholesterolaemia, 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. Diabetic women should be carefully monitored, especially during the initial stage of COC use. 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, the medication should be discontinued, and an alternative method of contraception should be used in order to determine if the depression is drug-related.
In case of suspected or confirmed venous thromboembolism (VTE) or arterial thromboembolism (ATE), Diva Continuo should be discontinued. In case of initiation of anticoagulant therapy, a suitable alternative method of contraception should be started due to the teratogenicity of anticoagulant therapy (coumarins).
Breastfeeding: COCs can affect breastfeeding by reducing the amount of breast milk and altering its composition, hence, you should stop using Diva Continuo until finishing breastfeeding. During the use of COCs, small amounts of contraceptive steroids and/or their metabolites may be excreted in the milk, which may affect the breastfeeding baby.
This medicine contains lactose. Patients with hereditary intolerance to galactose, Lapp lactase insufficiency, or poor absorption of glucose or galactose should not take this medicine.

Contraindications:
Hypersensitivity to any of the components of the formula.
Diva Continuo should not be administered in case of pregnancy or suspected pregnancy, presence or risk of venous thromboembolism (VTE) or arterial thromboembolism (ATE), presence or history of severe liver disease, severe renal insufficiency or acute renal failure, presence or history of liver tumours (benign or malignant), undiagnosed vaginal bleeding.
The risk of venous thromboembolism (VTE) may be caused by: 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 (VTE) , such as activated protein C (APC) resistance (including factor V Leiden), antithrombin III deficiency, protein C deficiency, protein deficiency: major surgery with prolonged immobilisation or existence of several risk factors.
The risk of arterial thromboembolism (ATE) may be caused by: current arterial thromboembolism (ATE), history of ATE (e.g., myocardial infarction) or prodromal condition (e.g., angina pectoris): cerebrovascular disease (current stroke, history of stroke, or prodromal condition such as transient ischaemic attack, TIA); known hereditary or acquired predisposition to arterial thromboembolism (ATE), such as hyperhomocysteinemia and antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant): History of migraine with focal neurological symptoms, existence of multiple risk factors or one severe risk factor (diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia).
This medicine is contraindicated in patients with breast cancer, whether known or suspected, or any other oestrogen-dependent malignancy. Diva Continuo is contraindicated in case of concomitant use of medicines containing ombitasvir/paritaprevir/ritonavir, and dasabuvir.

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. Other enzyme inducers such as barbiturates, bosentan, carbamazepine, primidone, ritonavir, nevirapine, efavirenz, felbamate, oxcarbazepine, topiramate, and products containing St. John's Wort (Hypericum perforatum) may also reduce contraceptive efficacy.
There is a potential risk of increased serum potassium in women taking drospirenone in combination with medicines that increase serum potassium concentration (ACE inhibitors, angiotensin II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, NSAIDs).
The use of oral contraceptives may affect the efficacy of the following medicines: cyclosporine, lamotrigine, tizanidine, theophylline, diazepam, and probably other benzodiazepines and tricyclic antidepressants.

Side effects:
Headaches, nausea, emotional lability, breast pain, amenorrhoea, and intermenstrual bleeding (spotting) may occur infrequently and exceptionally. Prolonged treatments may cause facial pigmentation to appear in susceptible patients, which may increase with sun exposure.
Depressive mood, nervousness, drowsiness, dizziness, paraesthesia, migraine, varicose veins, hypertension, abdominal pain, vomiting, dyspepsia, flatulence, gastritis, diarrhoea, acne, pruritus, skin rashes, back and limb pain, muscle cramps , vaginal candidiasis, pelvic pain, breast enlargement, fibrocystic breast, vaginal bleeding, genital discharge, hot flushes, vaginitis, menstrual disorder, dysmenorrhoea, hypomenorrhea, menorrhagia, vaginal dryness, decreased libido, asthenia, increased sweating, oedema, and weight gain have also been reported.

Presentation:
Packs containing 1 and 3 blisters with 28 white tablets.

Keep at room temperature (15 to 30°C).

In case of poisoning, seek medical assistance immediately.

Keep out of the reach of children.

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