CONTRACEPTIVES
Urufarma

Divina 28

Drospirenone 3.00 mg,
Ethinylestradiol 0.03 mg

Formula:
Each yellow coated tablet contains: Drospirenone 3.00 mg, ethinylestradiol 0.03 mg, and excipients (q.s.) Each red coated tablet contains: excipients (q.s.)

Therapeutic effect:
Contraceptive.

Indications:
Preventing pregnancy.
Taking one daily tablet of **Divina** ("the pill" for short) inhibits ovulation, alters the cervical mucus, induces changes in the endometrium, and alters tubal motility, thus preventing pregnancy.

Posology and method of administration:
Take **Divina 28** pills according to these instructions, no more than 24 hours apart, to achieve the highest contraceptive efficacy.
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. The order is as follows: take the 21 yellow pills first, then take the 7 red pills.
Start each new pack on the same day of the week when you took the first pill of the first pack.
Bleeding will occur while taking the red pills.
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: You should start the following packs on the same day of the week as the first pill of the first pack, using the same dosage regime: 21 yellow pills and then 7 red pills.
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. Birth control protection lasts the whole month, including days when you take the red pills.
What to do if you miss a pill: Missing a pill may expose you to getting pregnant.
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.
If you do not bleed after finishing 28 days of treatment, especially if you followed the treatment correctly, you need to make sure you are not pregnant before starting 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. The next cycle may last a few more days than the previous ones. 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.
These preparations should be avoided 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, since the risk of serious (cardiovascular) events would be significantly increased.
Serum potassium levels should be checked during the first cycle of treatment in patients receiving treatment with medicines that can increase serum potassium (ACE inhibitors, angiotensin II antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, NSAIDs).
Tell your doctor if you have recently given birth, had an abortion or miscarriage, 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, hypercholesterolemia, 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. 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. Patients who wear contact lens who develop visual changes while taking contraceptive medication or intolerance to contact lenses should be evaluated by an ophthalmologist.
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.
In case of suspected or confirmed VTE or ATE, stop taking **Divina 28**. In case of initiation of anticoagulant therapy, you should start using an alternative method of contraception due to the teratogenicity of the anticoagulant therapy (coumarins).
Breastfeeding: Combined oral contraceptives may affect breastfeeding by reducing the quantity of breast milk and changing its composition. Therefore, you should not use **Divina 28** until finishing breastfeeding. During the use of combined oral contraceptives (COCs), small amounts of contraceptive steroids and/or their metabolites may be excreted in the milk, which may affect the breastfeeding baby.

Contraindications:
Hypersensitivity to any of the components of the formula.
Divina 28 should not be administered in case of pregnancy or suspected pregnancy, liver disease, diabetes, arterial o venous disease, 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. This medicine is contraindicated in patients with breast cancer, whether known or suspected, or any other oestrogen-dependent malignancy.
Divina 28 is contraindicated in patients with kidney, liver, or adrenal failure.
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 ATE; history of thromboembolism (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, elevated risk of arterial thromboembolism due to multiple risk factors or the presence of a severe risk factor (diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia).
Divina 28 is contraindicated in case of concomitant use with medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir.

Interaction with other medicines:
Drugs 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 (including migraines), stomach aches, nausea, breast tension, depressive mood, or changes in body weight may occur infrequently and exceptionally. Prolonged treatments may cause facial pigmentation to appear in susceptible patients, which may increase with sun exposure. There have also been reports of intermenstrual bleeding, breast pain, mastalgia, vaginal discharge, vulvovaginal candidiasis, increased or decreased libido, vomiting, diarrhoea, acne, eczema, pruritus, alopecia, breast enlargement, vaginal infection, fluid retention, hypertension, hypotension.

Presentation:
Calendar pack containing 21 yellow coated tablets and 7 red coated 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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