miranda

Nomegestrol acetate 2.5 mg
Estradiol 1.5 mg

Formula:
Each white coated tablet contains: 2.5 g Nomegestrol acetate, 1.5 g Estradiol (as hemihydrate) and excipients q.s.
Each red coated tablet contains: excipients q.s.

Therapeutic action:
Prevention of pregnancy. Regulation of menstrual cycle.

Indications:
Prevention of pregnancy

Dosage and method of administration:
For maximum contraceptive effectiveness ***Miranda*** must be taken according to these instructions and at intervals of no more than 24 hours.

To start the treatment: Take by mouth the first table 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: Failure to take a tablet exposes the patient to the risk of conception. 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 combined 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 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 oral contraceptives is associated with increased risk of developing venous thromboembolism (VTE). However, VTE may also occur in patients who do not take oral contraceptives or are pregnant. Although the risk of VTE is higher in oral contraceptive users than in non-users, it is even higher 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.

Use in adolescents: There are no available data on the safety and efficacy in patients under 18 years of age.

Pregnancy and breast-feeding: Do not administer to patients who are or might be pregnant. In the event of conception during the administration period, consult your physician and interrupt the treatment.
Administration during breast-feeding is not recommended unless indicated by your physician.

Contraindications:
Hypersensitivity to any of the ingredients.
Miranda 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.
Miranda is contraindicated in patients with renal, hepatic or adrenal insufficiency.

Drug interactions:
Concomitant use with enzyme inducers (Rifampicin, Phenylbutazone, Phenytoin, Phenobarbital, Primidone, Carbamazepine, Topiramate, Felbamate, Griseofulvin), antibiotics (e.g. Amoxycillin) or Hypericum (St. John's wort) preparations may diminish contraceptive efficacy.
Likewise, HIV protease inhibitors with inducing potential (e.g. Ritonavir and Nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. Nevirapine and Efavirenz) may affect hepatic meabolism.
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, acne, reduced sex drive, mood changes, pelvic pain, 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 tablets and 4 red tablets.
Store at room temperature (15-30°C).
Keep out of the reach of children.