

Carmín

Desogestrel 0.075 mg

Formula:

Each coated tablet contains: 0.075 mg Desogestrel and excipients q.s.

Therapeutic action:

Oral contraceptive.

Indications:

Carmín is indicated for prevention of pregnancy. It is an oral contraceptive with Desogestrel as the active ingredient, and it can be used by women who are breast-feeding or are intolerant to estrogens.

Mechanism of action:

Carmín inhibits ovulation and increases the viscosity of the cervical mucus, hindering the passage of spermatozoa.

Dosage and method of administration:

For maximum contraceptive effect, take **Carmín** exactly according to these instructions. Take one tablet daily for 28 consecutive days, preferably at the same time each day. *Start of treatment:* Take the first tablet on Day 1 of the menstrual cycle (the first day of menstrual bleeding) followed by one tablet per day until all 28 tablets have been taken. Start a new blister pack on the day after you finish the previous one without interruption.

If the tablets were started precisely on Day 1 of the menstrual cycle, no other contraceptive method needs to be used. If they were not started on Day 1, but on the second day of menstruation, another means of contraception, preferably a barrier method (condom or diaphragm), must be used for at least 7 days. The second and subsequent treatment cycles must be started on the same day of the week as the first treatment cycle.

*Replacement of oral estrogen-progestogen contraceptive with **Carmín**:* Take the first tablet of **Carmín** on the day after you took the last (active) tablet of the combined oral contraceptive.

Replacement of progestogen-only contraceptive (mini-tablet, implant): Start **Carmín** at any time (without interruption) during treatment with the mini-tablet. Use a barrier contraceptive method for the first 7 days of treatment with **Carmín**.

Use after childbirth, miscarriage or termination of pregnancy: **Carmín** may be started immediately after a miscarriage or termination of pregnancy occurring in the first trimester. In this case there is no need to use complementary contraception methods. After childbirth, miscarriage or termination of pregnancy occurring in the second trimester, start taking **Carmín** tablets 21 to 28 days after childbirth, miscarriage or termination. If the tablets are started at a later date, use a barrier contraceptive method during the first 7 days of treatment. Patients who had intercourse before the start of treatment must rule out the possibility of pregnancy or wait until the next natural menstruation.

Forgotten or missed tablets: Failure to take a tablet exposes the patient to the risk of conception. If the forgotten tablet is remembered within 12 hours of the usual time, it must be taken immediately and the treatment continued as usual, taking the next tablet at the usual time.

If the missed tablet is remembered more than 12 hours after the time it is usually taken, the last missed tablet must be taken immediately (even if this means taking two tablets on the same day) and the treatment continued until the blister pack is finished. An additional non-hormonal (barrier: condom or diaphragm) contraceptive method must be used until a new pack is started.

Precautions and warnings:

Before taking oral contraceptives, a medical history must be taken and general physical and gynecological examinations must be given. Since different phenomena may present during oral contraceptive use, regular medical supervision is required, at least once yearly. Oral contraceptives do not protect against infection with HIV (AIDS) or other sexually transmitted diseases.

Pregnancy must always be ruled out before the start of treatment. Episodes of vomiting or diarrhea may reduce contraceptive effectiveness. An additional, non-hormonal (barrier: condom or diaphragm) contraceptive method is recommended.

Risks and benefits should be assessed in patients with a history of breast cancer and those diagnosed with breast cancer while using Desogestrel.

Women taking oral contraceptives are advised to stop smoking because of the increased risk of adverse cardiovascular events. Oral contraceptive use 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 significantly increased risk of serious (cardiovascular) events.

Bleeding may be more frequent, last longer, or occur only occasionally, or even cease completely. Vaginal hemorrhages must be carefully assessed in order to rule out malignant disease or pregnancy. Progestogens can modify peripheral insulin resistance and glucose tolerance; diabetic patients must therefore be adequately monitored.

All low-dose hormonal contraceptives may cause the formation of hypertrophic follicles which generally disappear spontaneously. Although they are generally asymptomatic they may be accompanied by mild abdominal pain and may occasionally require surgery.

In susceptible patients, long-term treatment can produce facial pigmentation, which may be exacerbated by exposure to the sun.

Treatment must be discontinued in the event of pregnancy. Patients who have migraines or severe headaches not previously experienced, liver disease, unusual pain and edema of the lower limbs, coughing or respiratory difficulty, significantly increased arterial pressure, immobility or sensory disorders, must discontinue the treatment and consult a physician without delay.

Progestogen-only contraceptives are not as effective as combined oral estro-progestogen contraceptives in preventing ectopic pregnancy.

Pregnancy / Lactation: *This drug is contraindicated in pregnant patients.*

Carmin has no adverse effects on the amount or quality of breast milk, and no effects have been found on the health of the breast-fed infant. Consequently, breast-feeding patients can safely use Desogestrel.

Drug interactions: No direct studies have been carried out on Desogestrel. Experience with other contraceptives indicates there may be interactions with Hydantoins, Barbiturates, Primidone, Carbamazepine and Rifampicin, and it is assumed interactions exist with Oxcarbazepine, Rifabutin, Troglitazone and Griseofulvin. Interactions appear to be based on the induction of hepatic enzymes by these drugs.

Concomitant use of these drugs can reduce the effectiveness of **Carmin**. A non-hormonal contraceptive method is recommended when any of these drugs are taken concomitantly with **Carmin**.

Contraindications:

Carmin is contraindicated in the event of known or suspected pregnancy, vaginal bleeding of unknown origin, hypersensitivity to any of the ingredients of the medicine, acute venous thromboembolic phenomena, past or present serious hepatic disease, and anomalies in liver function parameters.

Patients with hepatic tumours must not take Desogestrel, since a biological effect of progestogens on liver cancer cannot be excluded.

This medicine should not be taken in the presence of progestogen-dependent tumours.

Side effects:

Irregular menstrual bleeding has been reported. Bleeding can be more frequent, reduced or even cease completely. Bleeding may occur for extended periods. After several months of use, bleeding tends to become less frequent. The most commonly described side effects in clinical trials are as follows: irregular bleeding, acne, mood changes, breast pain, headaches, nausea and weight gain.

Presentation:

Blister pack containing 28 coated tablets.

Store at room temperature (15-30°C).

Keep out of the reach of children.