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Exeltis
Rethinking healthcare

Ciclomex

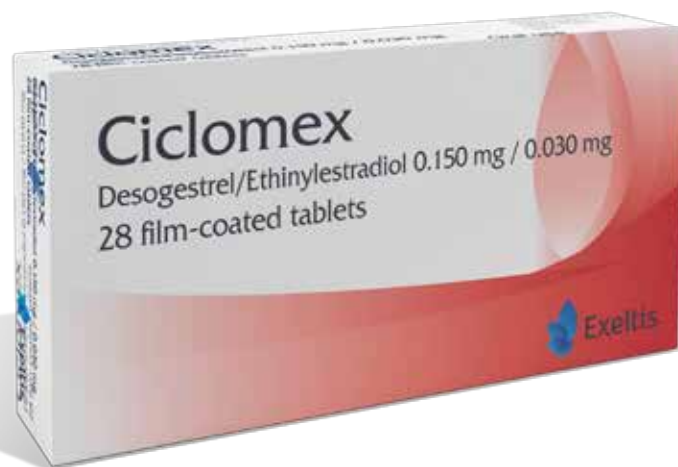
Desogestrel/Ethinylestradiol 0.150 mg / 0.030 mg
28 film-coated tablets

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- Pearl index of 0.04.¹
- Good cycle control.²
- Desogestrel has been demonstrated to have generally less pronounced effects on carbohydrate metabolism.³
- Minimal changes of the coagulation and fibrinolytic systems.⁴
- Favorable profile of reduced androgenic side effects.²



References: 1. AM J OBSTET GYNECOL 1993;168:1017-20. 2. AM J OBSTET GYNECOL 1993;168:1028-33. 3. Am J OBSTET GYNECOL 1993;168:1041-7. 4. AM J OBSTET GYNECOL 1993;168:1047-52.

Ciclomex® @ 0.150 mg/0.030 mg 28 film-coated tablets
Desogestrel / Ethinylestradiol

Indication: Ciclomex® is a contraceptive pill and is used to prevent pregnancy. **Composition:** A strip of Ciclomex® contains 21 white active tablets in the 1st, 2nd and 3rd rows of the strip and 7 green placebo tablets in row 4. Active tablets - The active substances are desogestrel and ethinylestradiol. Each white tablet contains 0.150 mg desogestrel and 0.030 mg ethinylestradiol. - The green tablets do not contain active substances. - The other ingredients are: White active tablets: lactose monohydrate, maize starch, povidone K-30 (E1201), d-alpha-tocopherol (E307), soybean oil, silica colloidal anhydrous (E551), stearic acid (E570) hypromellose 2910 (E464), triacetin (E1518), polysorbate, titanium dioxide (E171). Green inactive tablets: Lactose monohydrate, maize starch, povidone K-30 (E1201), silica colloidal anhydrous (E551), magnesium stearate (E572), hypromellose 2910 (E464), triacetin (E1518), polysorbate, titanium dioxide (E171), FD & C blue 2 aluminium lake (E132) and yellow iron oxide (E172). **Contraindications:** if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs; • if you know you have a disorder affecting your blood clotting - for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies; • if you need an operation or if you are off your feet for a long time; • if you have ever had a heart attack or stroke; • if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms); • if you have any of the following diseases that may increase your risk of a clot in the arteries: - severe diabetes with blood vessel damage, - very high blood pressure, - a very high level of fat in the blood (cholesterol or triglycerides), - a condition known as hyperhomocysteinaemia; • if you have (or have ever had) a type of migraine called 'migraine with aura'; • if you have or have recently had a severe liver disease; • if you have ever had a liver tumour; • if you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood; • known or suspected pregnancy; • if you have cancer affected by sex hormones - such as some cancers of the breast, womb lining or ovary; • if you have vaginal bleeding that has not been explained by your doctor; • if you are allergic (hypersensitive) to any of the ingredients in Ciclomex®. Do not use Ciclomex® if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Ciclomex®). **Possible side effects:** Like all medicines, Ciclomex® can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Ciclomex®, please talk to your doctor. An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. Serious side effects - see a doctor straight away. Signs of deep vein thrombosis include: • swelling of one leg or along a vein in the leg or foot especially when accompanied by; • pain or tenderness in the leg which may be felt only when standing or walking; • increased warmth in the affected leg; • change in colour of the skin on the leg e.g. turning pale, red or blue. Signs of a pulmonary embolism: • sudden unexplained breathlessness or rapid breathing; • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat; • severe pain in your stomach. If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold'). Signs of retinal vein thrombosis (blood clot in the eye): • Symptoms most commonly occur in one eye: • immediate loss of vision or painless blurring of vision which can progress to loss of vision. Signs of heart attack: • chest pain, discomfort, pressure, heaviness; • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats. Signs of a stroke: • sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke. Signs of blood clots blocking other blood vessels: • swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen). Signs of a severe allergic reaction to Ciclomex®: • swelling of the face, lips, mouth, tongue or throat. Signs of breast cancer include: • dimpling of the skin; • changes in the nipple; • any lumps you can see or feel. Signs of cancer of the cervix include: • vaginal discharge that smells and contains blood; • Unusual vaginal bleeding; • pelvic pain; • painful sex. Signs of severe liver problems include: • severe pain in your upper abdomen; • yellow skin or eyes (jaundice). If you think you may have any of these, see a doctor straight away. You may need to stop taking Ciclomex®. **Possible side effects:** Common (may affect up to 1 in 10 people): • Headache; • Putting on weight; • Breast problems, such as painful or tender breasts; • Depression or mood changes; • Stomach problems, such as nausea; abdominal pain; Uncommon (may affect up to 1 in 100 people): • Migraine (see a doctor as soon as possible if this is your first migraine or it's worse than usual, or if the headache is severe, unusual or long lasting); • Fluid retention (swollen hands, ankles or feet - a sign of fluid retention); • Decreased sexual desire; • Vomiting; • Diarrhoea; • Skin problems, such as rash or hives; • Breast enlargement; Rare (may affect up to 1 in 1000 people): • Changes in vaginal secretions - irregular vaginal bleeding, Bleeding between periods should not last long; • Breasts producing a milky fluid from the nipples; • Hypersensitivity reactions; • Discomfort of the eyes if you wear contact lenses; • Erythema nodosum (bruise-like swelling to the shins); • Erythema multiforme (this is a skin condition); • Decreased weight; • Increased sexual desire; • Harmful blood clots in a vein or artery for example: in a leg or foot (i.e. DVT); in a lung (i.e. PE); heart attack; stroke; mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA); blood clots in the liver, stomach/intestine, kidneys or eye. The chance of having a blood clot may be higher if there is any other conditions that increase this risk, like: • Severe allergic reaction to Ciclomex® • Breast cancer • Cancer of the cervix • Severe liver problems • High blood pressure • Gall stones • Chorea (a problem with the nervous system causing jerky movements that you can't control) • Worsening of systemic lupus erythematosus (SLE: when your immune system attacks your body causing, for example, joint ache and tiredness) • Stomach and intestine problems such as pancreatitis; Crohn's disease; ulcerative colitis • Worsening of otosclerosis (a hearing problem) • Problems with blood sugar • Worsening of a rare condition called porphyria • Worsening of skin problems, such as brown patches on your face or body (chloasma).

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