

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved.

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**
The dispensing of this medicine requires a doctor's prescription.
Read this package insert carefully in its entirety before using this medicine.
Keep this leaflet, you may need to read it again.
If you have further questions, please ask your doctor or pharmacist.

BELARA
TABLETS

Composition:
21 round, light pink tablets.
Each film-coated tablet contains:
Active ingredient and its quantity:
Ethinylestradiol 0.03 mg
Chlormadinone Acetate 2.00 mg

Inactive Ingredients:
Core: lactose monohydrate, maize starch, povidone K30, magnesium stearate
Film-coating: hypromellose, macrogol 6000, propylene glycol, talc, titanium dioxide (E171), red iron oxide (E172).

Each tablet contains 69.545 mg lactose.

Therapeutic group: Combined oral contraceptive

Therapeutic activity:
Contraceptive.
Belara is a hormonal contraceptive to be taken by mouth. Such oral contraceptives which contain two hormones are also called "combined oral contraceptives" (COC). The 21 tablets of a cycle pack contain the same amounts of both hormones, and therefore Belara is called a "monophasic preparation".
Oral contraceptives like Belara will not protect you against AIDS (HIV infection) or other sexually transmitted diseases. Only a condom can help to do this.

When should the preparation not be used?

Do not use this preparation if you are pregnant or suspect that you are pregnant.
Do not use this preparation if you are sensitive to any of its ingredients.
Do not use this preparation if you suffer or have suffered in the past from blood clots in the veins or arteries (e.g. deep vein thrombosis, pulmonary embolism, heart attack, stroke).
Do not use this preparation if you notice the first stages or signs of blood clots, inflammation of the veins or embolism, such as fleeting stabbing pain or swelling of the arms or legs, chest pain or feeling of tightness in the chest, sudden shortness of breath, sudden coughing of unknown cause.
Do not use this preparation if you are forced to rest for a long period of time (e.g. following an accident), before planned operation (at least 4 weeks before the scheduled date of the operation).
Do not use this preparation if you have diabetes and your blood sugar fluctuates uncontrollably or if you have changes in the blood vessels.
Do not use this preparation if your blood pressure rises and is difficult to control or if values are constantly above 140/90.
Do not use this preparation if you have disturbances of blood clotting (e.g. protein C deficiency).
Do not use this preparation if you suffer or have suffered in the past from inflammation of the liver (e.g. due to a virus) or from jaundice and your liver values have not yet returned to normal.
Do not use this preparation if you have stinging or itching all over your body or a bile flow disorder, particularly if this occurred in connection with a previous pregnancy or estrogen treatment.
Do not use this preparation if bilirubin values in your blood is raised (e.g. Dubin-Johnson or Rotor syndrome).
Do not use this preparation if you have a liver tumor or have had one in the past.
Do not use this preparation if you have severe stomach ache, an enlarged liver or signs of bleeding in the belly.
Do not use this preparation if porphyria (a disorder of "Heme" pigment metabolism) occurs.
Do not use this preparation if you suffer, have suffered or are suspected to have a hormone-dependent malignant tumor, e.g. breast or womb cancer.
Do not use this preparation if you suffer from severe disorders of fat metabolism.
Do not use this preparation if you suffer or have suffered in the past from inflammation of the pancreas associated with severe increase in blood fats (triglycerides).
Do not use this preparation if you suffer from a migraine for the first time.
Do not use this preparation if you suffer from unusually severe, long-lasting or frequent headache.
Do not use this preparation if you suffer from a migraine accompanied by disorders of sensation, perception and/or movement.
Do not use this preparation if you have sudden sight, hearing or movement disorders (in particular signs of paralysis).
Do not use this preparation if you notice worsening of epileptic seizures.
Do not use this preparation if you suffer from severe depression.
Do not use this preparation if you suffer from a certain type of deafness that became worse during previous pregnancies.
Do not use this preparation if for some unknown reason you had no period.
Do not use this preparation if you have an abnormal overgrowth of the inner layer of the womb (endometrial hyperplasia).
Do not use this preparation if for some unknown reason unusual bleeding occurs from the vagina.
Do not use this preparation if you are a smoker and over 35 years of age.
If one of these conditions occurs during administration of the pill, stop taking it immediately.

Do not take this medicine without consulting a doctor before starting treatment:

If you are breastfeeding (milk production may be reduced and its quality affected, very small amounts of the active substances pass into the milk).
If you suffer or have suffered in the past from heart or kidney disease, migraine, epilepsy or asthma, inflammation of the veins in the past, varicosis, multiple sclerosis, chorea (St. Vitus dance), muscular dystrophy, diabetes and a tendency towards it, liver disease in the past, disorders of fat metabolism, considerable overweight, high blood pressure, tetanus, benign tumor of the womb or benign overgrowth of the mucous membranes of the womb, breast disease (mastopathy), otosclerosis (mild ear deafness), history of pemphigus in pregnancy (a skin autoimmune disease that is characterized by blistering of the skin).

How will this medicine affect your daily life?

Smoking and taking hormonal contraceptives increase the risk of suffering from serious side effects in the heart and blood vessels. This risk increases with age and rising cigarette consumption, therefore if you intend to take hormonal contraceptives it is advisable to refrain from smoking, particularly if you are over 30 years of age. Women Smokers over the age of 35 years should use other contraceptive methods.
Women over the age of 40 years required special supervision since the tendency towards thrombosis increases with age.
Belara does not affect the ability to drive or operate machines.

Warnings:
Before using these pills you must undergo comprehensive general and gynecological examinations, and make sure that you are not pregnant. If there is a family history of diseases such as: thrombosis, deep vein thrombosis, pulmonary embolisms, stroke, sudden problems of perception, sensory perception, speech or movement, especially paralysis, myocardial infarction and angina pectoris, the patient should have her blood clotting system thoroughly checked.
If you have high blood pressure, abnormally high levels of fat in the blood (also if family history exists), if you are overweight or have diabetes the risk of serious side effects of hormonal contraceptives such as heart attack, embolism, stroke or liver tumors is increased. As usual with continued use of hormonal preparations, it is recommended to be under supervision and to undergo periodic checkups (including liver functions) according to the instructions of the attending doctor.
Following an abortion that occurred during the first three months of the pregnancy, you may commence treatment with Belara right away and there is no need for an additional contraceptive.

Following an abortion that occurred between the third and sixth month of pregnancy, if you are not breast feeding, you may commence treatment with Belara 21-28 days after, and there is no need to use an additional contraceptive. If more than 28 days have passed, you should use an additional mechanical contraceptive for the first 7 days. If sexual intercourse took place, then pregnancy should be ruled out or you should wait for the next period before commencing treatment with Belara.
Belara contains lactose, consult your doctor before use in cases of sensitivity to lactose.
If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions:
If you are taking another drug concomitantly, or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. The contraceptive effect of the pill may be affected if used concomitantly with medicines such as: Barbiturates, medicines for the treatment of tuberculosis (e.g. rifampicin, rifabutin), primidone, modafinil, medicines for the treatment of aids (e.g. ritonavir), griseofulvin, phenylbutazone, medicines for the treatment of epilepsy (e.g. carbamazepine, phenytoin and topiramate), St. Johns Wort (medicinal plant), certain antibiotics (e.g. ampicillin, tetracycline), medicines that affect bowel movement (e.g. metoclopramide) and activated charcoal, therefore, during concomitant use it is advisable to use an additional non-hormonal contraceptive method.
If you are using any medicine for diabetes, consult you doctor.
When using oral contraceptives, the excretion of diazepam, ciclosporin, theophylline or prednisolone may be reduced with the result that their effect may be greater. The effect of preparations containing clofibrate, paracetamol, morphine or lorazepam may be reduced if taken at the same time with the pills.

Side effects:
In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, such as: irregular menstruation, absence of menstruation, pain during menstruation, headache, dizziness, sensitivity of the breasts or secretion of milk from the breasts, nausea, vomiting, stomach ache, changes in body weight, mood changes and changes in sexual urge, rash, tiredness, visual disorders, acne, feeling of heaviness in the legs, changes in blood pressure, back and muscle pain, ovarian cysts, and in some cases inflammation or fungal infections of the vagina, diarrhea, hair loss, dry skin, tendency to sweet tastes, changes in blood fat values including increase in triglycerides.

Rare side effects: conjunctivitis, decrease in hearing ability, tinnitus, blood circulation disturbances, varicose veins, urticaria, dermatitis, itching, worsening of psoriasis, excessive hair, increased appetite, erythema nodosum (very rare).

Extended use of the pills may cause dark blotches to appear and therefore women with such a tendency must avoid exposure to the sun or to ultra-violet light.
The use of oral contraceptive pills increases the risk of venous and arterial thrombosis. Age, smoking, high blood pressure, blood coagulation problems in the family, unusual changes in fats and proteins (dysliproteinaemia), heart valve diseases, irregular heart rate, long periods of lack of mobility (e.g. following an accident or operation), significant overweight (BMI > 30 kg/m²), varicose veins and history of thrombosis, diseases that affect the blood circulation e.g. diabetes, Crohn disease, Sickle-cell anemia, may increase the risk.
Long term use of hormonal contraceptives may, in rare cases, speed up the possibility of formation of gallstones. There is a probability of a decrease in tolerance for contact lenses. Epidemiological studies demonstrated a very small increase in the frequency of breast cancer among women using contraceptive pills from a young age for a prolonged period.
In isolated cases breast secretion and enlargement have been observed. Laboratory test values may be affected, e.g. liver functions, adrenal and thyroid, and coagulation functions. Therefore, inform your doctor that you are taking Belara before performing blood tests.
If you have suffered from herpes during a previous pregnancy, this may recur during the use of a hormonal contraceptive.
A few studies have shown that there is a risk factor for cervical cancer in women suffering from the Human papilloma virus who take pills for a long period. However, it is unclear to what extent these studies results are affected by other factors (such as having sexual relations with more than one steady partner).
In rare cases benign (and even more rarely, malignant) liver tumors have been observed, that may cause dangerous internal bleeding, therefore, in the event of unusual abdominal pain that do not disappear quickly, consult your doctor as soon as possible!
In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Recommended dosage unless otherwise prescribed by your doctor:

Take the first tablet of the preparation on the first day of menstruation.
Remove the first tablet from the place in the packet marked for the corresponding day and swallow it (do not chew). Afterwards, continue taking the tablets in the direction of the arrows on the back of the aluminum foil. It is advisable to take the tablets at the same time every day (preferably in the evening) in order to ensure the effectiveness of the preparation. After taking the last tablet from the packet, do not take any tablets for 7 days, during which menstruation will appear, 2-4 days from taking the last tablet. If in exceptional cases bleeding does not occur during the days of the break, you may keep taking the tablets if pregnancy was ruled out during the first 10 days of the new menstruation. After the 7 day break, begin a new packet of the preparation, on the same day of the week that you started the previous packet, even if bleeding continues. The pill is effective as a contraceptive measure on the first day that you begin to take it and 7 days after you stop using it.

If irregular bleeding occurs:
Particularly in the first few months of taking hormonal contraceptives, irregular bleeding from the vagina may occur. If such irregular bleeding continues for more than three months or recurs after a regular cycle, consult your doctor.

If you are vomiting or have diarrhea:
The hormones contained in the pill are usually absorbed rapidly by the body. If vomiting and diarrhea occurs shortly after taking the daily pill (up to 4 hours afterwards), you should immediately take the next pill in the packet, thus shortening the monthly cycle by one day. If vomiting continues for over 12 hours, continue taking the pills as prescribed and add a non-hormonal contraceptive measure.


If you have taken more than the recommended dosage:
Severe poisoning due to taking a large number of pills at once is rare and is not life-threatening. The possible symptoms are mainly stomach or bowel complaints, disorders of the liver functions and vaginal bleeding. Preventive measures or countermeasures are necessary only in rare cases.

If you forget to take the daily tablet:
If you forget to take a tablet at the usual time, you must take it within the next 12 hours. If more than 12 hours have passed, the effectiveness and reliability of the preparation will be diminished during the current cycle. Therefore, you should continue taking pills from the current calendar pack at the usual time, and disregard those that you have forgotten, however during this cycle you should use additional non-hormonal contraceptive measures.

Directions for use:
Do not chew! Swallow the medicine with a small amount of water.

Avoid poisoning!
This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.
If you have taken an overdose, or if a child has accidentally swallowed this medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a doctor!
This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.
Do not give this medicine to your relatives, neighbors or acquaintances.
Do not take medicines in the dark! Check the label and the dose **each time** you take your medicine. Wear glasses if you need them.

Storage:
Store in a cool place.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

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Manufacturer: Gedeon Richter PLC., Budapest, Hungary  **GEDEON RICHTER**
License holder: Tec-O-Pharm-Libra Ltd., P.O.B. 45054 Jerusalem 91450
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