Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed according to a physician's prescription only

Belara

Film-coated tablets

Active Ingredients: Ethinylestradiol 0.030 mg, Chlormadinone acetate 2.0 mg
Inactive and allergic Ingredients: List of the additional ingredients detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your physician if you think you may have symptoms of a blood clot (see section 2 “Blood clots”).

1. What is the medicine intended for?

Belara is a hormonal contraceptive to be taken by mouth.
If such hormonal contraceptives contain two hormones like Belara, they are also called “combined hormonal contraceptives” (CHCs). The 21 tablets of a cycle pack contain the same amounts of both hormones, and therefore Belara is also called a "monophasic preparation".
Belara, like other hormonal contraceptives, will not protect you against AIDS (HIV infection) or other sexually transmitted diseases. Only condoms help to do this.

Therapeutic group: sex hormones and modulators of the genital system, progestogens and estrogens, fixed combinations.

2. Before using the medicine

General notes
Before you start using Belara you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 “Blood clots”.

Before you start taking Belara, your physician will conduct a thorough general and gynaecological examination, rule out pregnancy, and, taking into account the contraindications and precautions, decide whether Belara is suitable for you. This examination should be carried out every year, while you are taking Belara.

Do not use the medicine if:

You should not use Belara if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your physician. Your physician will discuss with you what other form of birth control would be more appropriate.

- if you are allergic to ethinylestradiol or chlormadinone acetate or any of the other ingredients of this medicine (listed in section 6);
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolism, PE) or other organs;
- if you notice the first stages or signs of a blood clot, inflammation of the veins or embolism, such as transient brain circulatory disturbance, fleeting stabbing pain, chest pain or feeling of tightness in the chest;

- 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 mutation or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have diabetes and your blood sugar fluctuates uncontrollably;
- if you have high blood pressure which is difficult to control or if your blood pressure rises considerably (values constantly above 140/90 mm Hg);
- if you have ever had a heart attack or a 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 temporary disturbance of the blood flow of the brain [TIA – transient ischaemic attack]);
- 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 suffer from inflammation of the liver (e.g. due to a virus) or from jaundice and your liver function values have not yet returned to normal;
- if you have itching all over your body or you suffer from a bile flow disorder, particularly if this occurred in connection with a previous pregnancy or oestrogen treatment;
- if the level of bilirubin (a degradation product of blood pigment) in your blood is elevated, e.g. due to an inborn metabolic disorder (Dubin-Johnson syndrome or Rotor syndrome);
- if you have meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull);
- if you have a liver tumour, or have had one in the past;
- if you have severe stomach ache, an enlarged liver or notice signs of bleeding in the belly;
- if porphyria (disorder of blood pigment metabolism) occurs for the first time or recurs;
- if you have or have had or if you are suspected to have a hormone-dependent malignant tumour, e.g. cancer of the breast or womb;
- if you suffer from severe disorders of fat metabolism;
- if you suffer or have suffered from inflammation of the pancreas and this is associated with severe increase in blood fats (triglycerides);
- if you suffer from unusually severe, frequent, or long-lasting headache;
- if you have sudden perception disturbances (sight or hearing);
- if you have movement disorders (in particular signs of paralysis);
- if you notice worsening of epileptic fits;
- if you suffer from severe depression;
- if you suffer from a certain type of deafness (otosclerosis) that became worse during previous pregnancies;
- if for some unknown reason you had no period;
- if you have an abnormal overgrowth of the inner layer of the womb (endometrial hyperplasia);
- if for some unknown reason bleeding occurs from the vagina.

Do not use Belara if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir , dasabuvir ,glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Belara).

If any of these conditions occurs while taking Belara, stop taking Belara immediately.
You must not take Belara, or must stop taking it immediately, if you have a serious risk or several risks of blood clotting disorders.

Special warnings regarding the use of the medicine
Talk to your physician or pharmacist before using Belara.

When should you contact your physician?
Seek urgent medical attention
- If you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clot (thrombosis) section below).

For a description of the symptoms of these serious side effects, please go to "How to recognise a blood clot".

Tell your physician if any of the following conditions apply to you.
If the condition develops, or gets worse while you are using Belara, you should also tell your physician.

- If you smoke. Smoking increases the risk of serious side effects to the heart and blood vessels during the use of combined hormonal contraceptives. This risk increases with age and increasing cigarette consumption. This applies particularly to women over the age of 35. Smokers over the age of 35 years should use other contraceptive methods.
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- If you have high blood pressure, abnormally high levels of fat in your blood, if you are overweight, or have diabetes. In this case, the risk of serious side effects of combined hormonal contraceptives (such as heart attack, embolism, stroke or liver tumours) is increased.
- If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- If you have systemic lupus erythematosus (SLE –; a disease affecting your natural defence system);
- If you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting that causes kidney failure);
- If you have sickle cell anaemia (an inherited disease of the red blood cells);
- If you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing inflammation of the pancreas (pancreatitis);
- If you need an operation, or you are off your feet for a long time (see in section 'Blood clots (thrombosis)');
- If you have given birth recently, you are at an increased risk of blood clots. You should ask your physician how soon after delivery you can start taking Belara;
- If you have an inflammation of the veins under the skin (superficial thrombophlebitis);
- If you have varicose veins.

BLOOD CLOTS
Using a combined hormonal contraceptive such as Belara increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop
- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Belara is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	**What are you possibly suffering from?**

- 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
	Deep vein thrombosis

- 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 physician 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').	Pulmonary embolism
Symptoms most commonly occur in one eye: - immediate loss of vision or - painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
- 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	Heart attack

- 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.	Stroke
- swelling and slight blue discolouration of an extremity; - severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely, a clot may form in a vein in another organ, such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.
After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.
When you stop Belara your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lung (DVT or PE) with Belara is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- It is not yet known how the risk of a blood clot with Belara compares to the risk with a combined hormonal contraceptive that contains levonorgestrel.
- The risk of having a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot” below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Belara	Not yet known.

If you notice an increase in frequency or intensity of migraine attacks during the use of Belara (which may indicate a disorder in the blood supply to the brain), consult your physician as soon as possible. It is possible that your physician will advise you to stop taking Belara immediately.

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with Belara is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30 kg/m^2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Belara may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Belara ask your physician when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago;

The risk of developing a blood clot increases the more conditions you have.
Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.
It is important to tell your physician if any of these conditions apply to you, even if you are unsure. Your physician may decide that Belara needs to be stopped.
If any of the above conditions change while you are using Belara, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your physician.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?
Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using Belara is very small but can increase:
- with increasing age (beyond about 35 years);
- **if you smoke**. When using a combined hormonal contraceptive like Belara you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your physician may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;

- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation)
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Belara, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your physician.

- ***Development of tumours***

Some studies show that there is a risk of cancer of the neck of the womb in women whose neck of the womb is infected by a certain sexually transmitted virus (human papilloma virus) and who take the pill for a long time. However, it is unclear to what extent these results are affected by other factors (e.g. differences in the number of sexual partners or in the use of mechanical contraceptive methods).

Studies reports showed a slightly increased risk of breast cancer in women who are currently using CHCs. During the course of 10 years after cessation of CHC use, this increased risk gradually returns to the age-related background risk. Because breast cancer is rare in women under the age of 40 years, the higher number of breast cancer diagnosed in current and recent CHC users is small in relation to the overall risk of breast cancer.

In rare cases benign, and even more rarely malignant, liver tumours have occurred after taking hormonal contraceptives. These may cause dangerous internal bleeding. In the event of severe pain in the stomach region, that does not disappear on its own, consult your physician.

Use of chlormadinone acetate has been linked to the development of a generally benign tumour of the tissue layer between the brain and the skull (meningioma). The risk increases especially when you use it at high doses for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with Belara (see section ‘Do not take Belara’). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

- ***Other Diseases***

Psychiatric disorders
Some women using hormonal contraceptives including Belara have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your physician for further medical advice as soon as possible.

Many women have a slight increase in blood pressure while taking hormonal contraceptives. If your blood pressure rises considerably while taking Belara, your physician will advise you to stop taking Belara and prescribe a medicine to lower your blood pressure. As soon as your blood pressure has returned to normal, you can start taking Belara again.

If you have suffered from herpes during a previous pregnancy, this may recur during the use of a hormonal contraceptive.

If you have a certain disorder of the blood fat levels (hypertriglyceridaemia) or this has occurred in your family, you are at an increased risk of the inflammation of the pancreas. If you have acute or chronic liver dysfunction, your physician may tell you to stop taking Belara until your liver values have returned to normal. If you had suffered from jaundice during a

previous pregnancy or while using a hormonal contraceptive and it reappears, your physician will advise you to stop taking Belara.

If you are a diabetic and your blood sugar is kept under control with medicine(s), and you take Belara, your physician will examine you carefully, as long as you are taking Belara. It might be necessary to alter your diabetic treatment.
Uncommonly brown patches may appear on your skin (chloasma), especially if you had them during a previous pregnancy. If you know you have a predisposition, you should avoid direct sunlight and ultraviolet radiation while taking Belara.

- ***Diseases which may be negatively affected***

Special medical supervision is also necessary,
- if you have epilepsy;
- if you have multiple sclerosis;
- if you have severe muscle cramps (tetany);
- if you have migraine;
- if you have asthma;
- if you have a weak heart or kidneys do not work correctly;
- if you have St. Vitus dance (chorea minor);
- if you are diabetic;
- if you have a liver disease;
- if you have a disorder of fat metabolism;
- if you have diseases of the immune system (including systemic lupus erythematosus);
- if you are considerably overweight;
- if you have high blood pressure;
- if you have endometriosis (the tissue that lines the cavity of your womb, called the endometrium, is found outside this lining layer);
- if you have varicose veins or inflammation of the veins;
- if you have blood clotting problems (see section 2);
- if you have a disease of the breasts (mastopathy);
- if you have benign tumour (myoma) of the womb;
- if you had herpes (herpes gestationis) during a previous pregnancy;
- if you have depression;
- if you have chronic inflammation of the bowels (Crohn´s disease, ulcerative colitis).

Please consult your physician if you have, or have had in the past, any of the above mentioned diseases, or if any of them occurs while you are taking Belara.

- ***Effectiveness***

If you do not take the contraceptive pill regularly, or you vomit or have diarrhoea after taking a pill, or you take certain medicines at the same time, the contraceptive effect may decrease.
In very rare cases metabolic disorders may impair contraceptive efficacy.
Even if you take hormonal contraceptives as directed, complete birth control is not guaranteed.

- ***Irregular bleeding***

Particularly, in the first few months of taking hormonal contraceptives, irregular vaginal bleeding (breakthrough bleeding/spotting) may occur. If such irregular bleeding continues to occur for 3 months, or recurs after previously regular cycles, please consult your physician. Spotting may also be a sign of a reduced contraceptive effect. In some cases, withdrawal bleeding may be absent after Belara has been taken for 21 days. If you have taken Belara according to the instructions in section 3 below, it is unlikely that you are pregnant. If Belara was not taken as instructed before withdrawal bleeding was absent for the first time, pregnancy must be ruled out for sure before any further use.

Children and adolescents

Belara is only indicated after the first menstruation. The safety and efficacy of Belara in adolescents below 16 years has not been established.

Elderly
Belara is not indicated after menopause.

Other medicines and Belara
Tell your physician or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescription medicines and nutritional supplements.

Do not use Belara if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir , glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme). Your physician will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
Belara can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Belara”.

Some medicines can have an influence on the blood levels of Belara and make it **less effective in preventing pregnancy**, or may cause unexpected bleeding. These include medicines used for the treatment of
- epilepsy (such as barbiturates, carbamazepine, phenytoin, topiramate, felbamate, oxcarbazepine, barbexaclone, primidone),
- tuberculosis (e.g. rifampicin, rifabutin),
- sleeping disorder (modafinil),
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors, such as ritonavir, nevirapine, efavirenz),
- fungal infections (griseofulvin),
- high blood pressure in the blood vessels in the lung (bosentan),
- herbal preparations containing St John's-wort (*Hypericum perforatum*). If you want to use herbal products containing St. John’s wort while you are already using Belara you should consult your physician first.

Medicines that stimulate bowel movement (e.g. metoclopramide) and activated charcoal may affect the absorption of the active substances of Belara and reduce their effects.

During treatment with these medicines you must use additional mechanical contraceptive methods (e.g. condoms). The additional mechanical contraceptive methods must be used during the whole time of the concomitant drug therapy and for 28 days after the end of treatment. If the concomitant drug therapy runs beyond the end of the tablets in the current CHC pack, the next pack of Belara should be started right after the previous one without the usual tablet-free interval.

If long-term treatment with the above mentioned medicines is necessary, you should use non-hormonal contraceptive methods. Ask your physician or pharmacist for advice.

Interactions between Belara and other medicines can increase or intensify the side effects of Belara. The following medicines can adversely affect the tolerability of Belara:
- ascorbic acid (a preservative, also known as vitamin C),
- paracetamol (providing pain relief and controlling fever),
- atorvastatin (lowering high cholesterol levels),
- troleandomycin (an antibiotic),
- imidazole antifungal agents – e.g. fluconazole (to treat fungal infections),
- indinavir (a preparation to treat HIV infection).

Belara may influence the effect of other medicines.
Belara may increase the efficacy or decrease the tolerability of the following medicines:
- some benzodiazepines, e.g. diazepam (for treatment of sleep disturbances),

- ciclosporin (a medicine that suppresses the immune system),
- theophyllline (treatment of symptoms of asthma),
- corticosteroids, e.g. prednisolone (known as steroids, anti-inflammatory medicines of e.g. Lupus, arthritis, psoriasis).

Belara may reduce the efficacy of the following medicines:
- lamotrigine (for the treatment of epilepsy),
- clofibrate (lowering high cholesterol levels),
- paracetamol (providing pain relief and controlling fever),
- morphine (a specific strong analgesic – providing pain relief),
- lorazepam (used to treat anxiety disorders).

Please also read the package leaflets of the other prescribed preparations.

Inform your physician if you are taking insulin or other medicines to lower your blood sugar. The dosage of these medicines may have to be changed.

Please remember that the above details also apply if you have taken any of these active substances shortly before you start taking Belara.

Administration of Belara may affect the result of some laboratory tests of the liver, kidney, adrenal and thyroid functions, certain blood proteins, carbohydrate metabolism and blood clotting. Changes generally remain within the normal laboratory range. Please tell your doctor that you are taking Belara before having a laboratory test.

Pregnancy and breast-feeding
Do not use this medicine if you are pregnant of think you might be pregnant.

Belara is not recommended during pregnancy. If you become pregnant while taking Belara, you must stop taking it immediately. Previous use of Belara, however, does not justify an abortion.

If you take Belara, you must remember that milk production may be reduced, and its quality may be affected. Very small amounts of the active substances pass into the milk. Hormonal contraceptives such as Belara may only be used after discontinuing lactation.

Driving and using machines
Combined hormonal contraceptives are not known to have negative effects on the ability to drive or to operate machines.

Important information regarding some of the ingredients of the medicine
Belara contains lactose. If you have been told by your physician that you have an intolerance to certain sugars, contact your physician before taking this medicine.

3. How should you use the medicine?

Always take this medicine exactly as your physician told you. Check with your physician or pharmacist if you are not sure.
Do not exceed the recommended dose.

Mode of administration
Belara is to be taken by mouth.

How and when should you take Belara?
Press out the first tablet at the position on the cycle pack which is marked with the corresponding day of the week (e.g. "Sun" for Sunday) and swallow it without chewing. You then take one tablet every day, following the direction of the arrow, if possible at the same time of day, preferably in the evening. If possible, the interval between taking two tablets should always be 24 hours. The days printed on the cycle pack allow you to check every day whether you have already taken the tablet for that particular day.
Take one tablet daily for 21 consecutive days. Afterwards, there is a break of seven days. Normally, 2-4 days after taking the last tablet, withdrawal bleeding similar to your menstrual

period will start. After the seven-day break, continue taking the tablets from the next cycle pack of Belara, regardless of whether the bleeding has or has not stopped.

When may you start taking Belara?
If you have not taken any hormonal contraceptives before (during the last menstrual cycle)
Take your first tablet of Belara on the first day of your next menstrual period.
Contraception begins on the first day of administration and lasts throughout the seven-day break.

If you have had a miscarriage or abortion in the first three months of pregnancy
After a miscarriage or abortion you can start taking Belara immediately. In this case you do not have to use any additional contraceptive methods.

If you have given birth or had a miscarriage in the 3rd - 6th months of pregnancy
If you are not breast-feeding, you may start taking Belara 21-28 days after delivery. You do not have to use any additional contraceptive methods.
If, however, more than 28 days have passed since birth, you must use additional contraceptive methods for the first seven days.
If you have already had sexual intercourse, you must rule out pregnancy or wait until your next period before you start taking Belara.

Do not forget that you should not take Belara if you are breast-feeding (see section "Pregnancy and breast-feeding").

How long may you take Belara?
You may take Belara for as long as you need hormonal contraception, and as long as it is not limited by risks to your health. After you stop taking Belara, the beginning of your next period may be delayed by about a week.

What should you do if vomiting or diarrhoea occurs *while taking Belara?*
If vomiting or diarrhoea occurs within 4 hours after you have taken a tablet, it is possible that the active substances of Belara are not completely absorbed. The situation is almost the same as having forgotten to take a tablet, and you have to take a new tablet from a new blister pack immediately. If possible, take the new tablet within 12 hours after the last tablet intake and continue taking Belara at the usual time. If this is not possible, or more than 12 hours have passed already, proceed according to section “If you forget to take Belara”, or contact your physician.

If you take more Belara than you should
There is no evidence suggesting that severe signs of poisoning occur after taking a large number of tablets in one dose. Nausea, vomiting, and, particularly in young girls, slight bleeding from the vagina may occur. In these cases, consult a physician. If necessary, the physician will check your salt and water balance, and liver function.
If a child has accidently swallowed the medicine, proceed immediately to the hospital emergency room and bring the package of the medicine with you.

If you forget to take Belara
If you forget to take the tablet at the usual time, you must take it within the next *12 hours* at the latest. In this case, no other contraceptive methods are necessary and you may continue taking the tablets as usual.

If the interval is *longer than 12 hours*, the contraceptive effect of Belara is no longer ensured. In this case, you must use additional mechanical contraceptive methods (e.g. condoms) during the next seven days.

If you want to delay your menstrual period
Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new cycle pack of Belara instead of the tablet-free period, to the end of the second strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this second cycle pack. After the usual tablet-free period of 7 days, continue with the following cycle pack.

You might ask your doctor for advice before deciding to delay your menstrual period.

If you want to change the first day of your menstrual period
If you take the tablets according to the instructions, then your menstrual period/withdrawal bleed will begin in the tablet-free week. If you have to change this day, you do this by making the tablet-free period shorter (but never longer!). For example, if your tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new cycle pack 3 days earlier than usual. If you make the tablet-free period very short (for example, 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience spotting (droplets or flecks of blood) or breakthrough bleeding.
If you are not sure how to proceed, contact your doctor for advice.

You should persist treatment as recommended by the physician.

If you stop taking Belara
When you stop taking Belara, your ovaries soon will resume their full activity, and you may become pregnant.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, ask your physician or pharmacist.

4. Side effects

As with any medicine, use of Belara may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of 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 Belara, please talk to your physician.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section “Warnings and precautions”).

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. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2: “What you need to know before you use Belara”.

The frequencies with which side effects have been reported are defined as follows:
Very common adverse events (may affect more than 1 in 10 people):
Nausea, vaginal discharge, pain during menstruation, absence of menstruation.

Common adverse events (may affect up to 1 in 10 people):
Depression, nervousness, irritability, dizziness, migraine (and/or aggravation of it), visual disturbances, vomiting, acne, feeling of heaviness, pain in the belly, tiredness, accumulation of water, increase in weight, increase in blood pressure.

Uncommon adverse events (may affect up to 1 in 100 people):
Fungal infections of the vagina, benign changes in the connective tissues of the breasts, drug hypersensitivity including allergic skin reaction, changes in blood fats including increased triglycerides, decrease in libido, stomach ache, rumbling in the bowels, diarrhoea, pigmentation problems, brown blotches on the face, hair loss, dry skin, tendency to sweat, back pain, muscle problems, secretion from the breasts.

Rare adverse events (may affect up to 1 in 1,000 people):
Inflammation of the vagina, increased appetite, conjunctivitis, discomfort when wearing contact lenses, sudden hearing loss, tinnitus, high blood pressure, low blood pressure, blood circulation collapse, varicose veins, hives, eczema, redness of the skin, itching, worsening of

existing psoriasis, excessive hair growth on the body or in the face, enlargement of the breasts, inflammation of the vagina, longer and/or more intense menstruation, pre-menstrual syndrome (physical and emotional problems before the start of menstruation).

Harmful blood clots in the 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 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 you have any other conditions that increase this risk (see section 2 for more information on the conditions that increase the risk of blood clots and the symptoms of a blood clot).

Very rare (may affect up to 1 in 10,000 people):
Erythema nodosum (reddish lumps on the skin).

In addition, the following adverse reactions have been reported in the post-marketing period with ethinylestradiol and chlormadinone acetate: weakness and other allergic skin reactions not related to immune system diseases.

The use of combined hormonal contraceptives has also been linked with an increase of risks for serious diseases and side-effects:

- risk of blockage of the veins and arteries;
- risk of diseases of the bile tract;
- risk of tumours (e.g. liver tumours, which in isolated cases may cause life-threatening bleeding in the abdominal cavity, cancer of the neck of the womb or breasts);
- aggravation of chronic inflammation of the bowels (Crohn's disease, ulcerative colitis).

If a side effect appears, if one of the side effects worsens or if you suffer from any side effect not mentioned in the leaflet, you should consult the physician.

Reporting of side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) which refers you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/.

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed by the physician.
- Do not use this medicine after the expiry date (Exp. date) appearing on the carton. The expiry date refers to the last day of that month.
- Store below 30°C.

6. Additional information

What Belara contains
- In addition to the active ingredients Belara also contains:
  Tablet core: Lactose monohydrate, maize starch, povidone K30, magnesium stearate.
  Film-coating: Hypromellose, lactose monohydrate, macrogol, propylene glycol, talc, titanium dioxide, red iron oxide.

What Belara looks like and contents of the pack

Round, pale pink, biconvex film-coated tablet.
1x21 or 3x21 film-coated tablets are packed into PVC/PVDC/Al blister pack and cardboard box.

License Holder:
TEC-O-Pharm Ltd. P.O. Box 45054 Jerusalem

Manufacturer:
Gedeon Richter PLC.,
19 - 21 GYOMROI UT, BUDAPEST, H - 1103, HUNGARY
Registration number of the medicine in the National Drug Registry of Ministry of Health:
127-34-30410-00

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