Bromocriptine prevents the secretion of the hormone prolactin. Prolactin is a hormone which creates anterior pituitary, small glands located in the central nervous system in the base of skull. The high levels of prolactin in the blood can be made without any particular reason, such a result of the effect of certain medicines, diseases of the pituitary gland or pituitary gland-related disorders. Bromocriptine is used for the treatment of diseases caused by high levels of hormones prolactin in the blood, thus preventing its excessive secretion from the pituitary. Bromocriptine does not affect the secretion of other pituitary hormones, however, effectively reduces the level of growth hormone in the blood of patients with acromegaly. Bromocriptine is used for the treatment of acromegaly, a disease which occurs as a result of excessive secretion of growth hormone and exerts a disproportionate enlargement of the extremities (lower jaw, hands, feet, ears and nose). Bromocriptine increases the production of dopamine in the central nervous system. Bromocriptine is also used in the treatment of Parkinson’s disease. Parkinson’s disease is manifested deficiency of dopamine in certain areas of the central nervous system. Dopamine is a substance in the brain that plays an important role in the coordination (alignment) of movement. In patients with Parkinson’s disease, bromocriptine reduce tremor (shaking), rigidity (stiffness), dyskinesia (a disorder in speed and coordination of motor function) and postural disability (maintaining upright posture disorder). Bromocriptine normalize ovarian function, ie the ratio between the endocrine glands, and the pituitary gland, and because of that the bromocriptine is used in the treatment of disorders of the menstrual cycles in women.

**Medicines use (Indications)**

Bromocriptine is used in the treatment of:
• Patients with high levels of prolactin in the blood hormone which causes decreased activity—gonadal and consequently infertility, impotence (impotence) or disturbances milk secretion, disorders of the menstrual cycle in women;
• Women after childbirth or abortion when it comes to health reasons prevent lactation (generation or secretion of milk) and breast-feeding;
• Inflammation of the mammary glands which is usually occur in the breast feeding, but can occur independently of the pregnancy or childbirth. In such cases, bromocriptine is used for the prevention of milk production in the mammary gland.
• Breast disease or breast pain in some phases of the menstrual cycle;
• Benign tumor of the pituitary gland that causes excessive secretion of prolactin
• Acromegaly, a disease which occurs as a result of excessive growth hormone secretion
• Parkinson's disease

Other indications

There is little data on the effectiveness of bromocriptine in the treatment of symptoms and premenstrual benign breast disease, which is why its use in this condition does not recommended.

Warning and precautions

Bromocriptine can not use in:

• Patients hypersensitive to bromocriptine or the other excipients of the medicine
• Patients hypersensitive to ergot alkaloids (alkaloids of rye principal)
• Patients with uncontrolled hypertension (high blood pressure)
• Pregnant women with hypertension (high blood pressure), including eclampsia (sudden increase in blood pressure with the emergence of attacks similar to epilepsy), preeclampsia (a condition prior to the rapid increase blood pressure) or hypertension (high blood pressure) caused by pregnancy
• Patients with hypertension (high blood pressure) after childbirth and puerperium (the period after childbirth for up to 6 weeks)
• Patients with coronary disease, existing coronary valves diseases or other severe diseases of the cardiovascular system (heart and blood vessels)
• Patients with echocardiography (ultrasound) confirmed the cardiac valvulopathy (disease of heart valves) that require long-term treatment of bromocriptine
• Patients who have or had severe mental disorders.

Hypersensitivity (allergic) means that while taking the medicine showed some or all of this signs: skin rash, itchy skin, swelling of extremities, swelling of the face, lips, tongue and/or throat for which the patient swallows or breathes hard. In this case you should immediately consult a doctor. Before the treatment, the doctor should be informed of all health problems you had or do you have: heart and blood vessels disease, kidney and liver disease, metabolic or other chronic diseases, and whether you have a known allergy (hypersensitivity). Warn you doctor if you have or have ever had an ulcer (ulcer) in the digestive system. If you notice indigestion or gastrointestinal bleeding during treatment, immediately inform physician, who will, if it is necessary, to discontinue treatment with bromocriptine. Since it sometimes, especially in the first days of treatment, can occur hypotension (low blood pressure), which can cause decreased attention, you have to be especially careful when you are driving and/or operating machinery. The physician will monitor your blood pressure, particularly during the initial months of therapy. Application of bromocriptine may be accompanied by sleepiness and sudden sleep phenomena, particularly in
patients with Parkinson's disease. Sudden sleep during the performance of daily activities (sometimes without warning signs), very rarely occurs. If it appear drowsiness or sudden sleep during the treatment with bromocriptine you can not drive and/or operate machinery. The patients take the long-term use there is a high dose of bromocriptine increased the risk of fibrosis (creating connective tissue). Before the start of the long-term bromocriptine treatment, the doctor will check the function of the heart (ultrasound), and lung digestive system. In some patients, particularly those who have taken a long time very high doses of bromocriptine, were observed pleural (effusion in lung lining) and pericardial effusions (effusion in pericardium), pleural fibrosis (creation of connective tissue in the pulmonary coating), and pulmonary fibrosis (creation of connective tissue in the lungs), and pericarditis constriction (bonding changes of pericardium with pressure on the heart). In case of unexplained pleural or lung lesions, the physician will carefully reviewed and, if it is necessary, discontinue treatment with bromocriptine. The small number of patients, particularly in those who were treated with high-dose long-term bromocriptine, retroperitoneal fibrosis was observed (the creation of the connective tissue in the area of behind the peritoneum). The first symptoms of retroperitoneal fibrosis are back pain, swelling of the lower limbs and decreased kidney function. If you notice any of these symptoms, immediately inform doctor. If a doctor suspects the occurrence of retroperitoneal fibrosis or confirm the diagnosis, he will probably discontinue the treatment with bromocriptine. Pathological gambling, increased libido and hypersexuality have been reported in patients with Parkinson's disease who were taking medication which are dopamine agonists, including bromocriptine. These effects are usually reversible after dose reduction or discontinuation of therapy.

Women after childbirth

In rare cases, patients after childbirth who took bromocriptine for prevention of lactation (production and secretion of milk), serious adverse events were observed, including hypertension (high blood pressure), myocardial infarction (heart attack), epilepsy attack, stroke or mental disorders. In some patients severe headache and/or transient visual disturbances preceded the seizures of epilepsy or stroke. Although a causal connection between bromocriptine and these phenomena are not confirmed in women after childbirth while taking bromocriptine for the prevention of lactation (production and secretion of milk), as well as in patients treated with bromocriptine for any other reason, the doctor will measure your blood pressure regularly. If the occurrence of hypertension (high blood pressure) and heavy, advancing and persistent headache (with or without visual disturbances) or a toxic effect on the central nervous system, the doctor will carefully assess the health status of patients and discontinue a treatment with bromocriptine. Medication which may affect the blood pressure, such as: sympathomimetics (medicines that stimulate the central nervous system), or ergot alkaloids (alkaloids of rye principal) including ergometrine or methilergometrine. In the puerperium (the period after childbirth for up to 6 weeks) does not recommended concomitant use of bromocriptine and these medicines. The safety and efficacy of use of bromocriptine in patients with heart disease and cardiovascular system and liver and kidney disease has not been confirmed. Special caution is required in the treatment of patients with Raynaud's syndrome (peripheral circulatory disease) and in patients with mental disorders.

Patients with prolactinoma (pituitary gland tumor)

With regard to the patients with tumors of the pituitary gland could develop hypopituitarism (insufficiently the secretion of pituitary gland hormones) caused by the pressure of the pituitary gland or tissue damage prior to application bromocriptine, your doctor will do a complete
assessment of pituitary function and introduce appropriate replacement therapy. In patients with pituitary tumors should carefully monitor changes in tumor size. If the tumor continues to expand it should consider a surgical method of treatment. If a patient with pituitary tumor, determine pregnancy after the administration of bromocriptine, pregnancy should be carefully monitored. Tumors of the pituitary gland with an increased production of prolactin during pregnancy can be increased. In these patients, treatment with bromocriptine often reduces tumor and rapidly improves disorders of the visual field. In severe cases, because of pressure of tumors on the optic nerve or other nerves in the head, may require urgent surgical intervention on the pituitary gland. The disorder of the visual field is known complication of pituitary tumors. Treatment with bromocriptine often remove a visual disturbances. However, in some patients it may aggravate excesses of the visual field, which can be improved by reducing the dose of bromocriptine. Doctor will continue to monitor changes in the visual field, in order to timely adjust the dose. Tell your doctor if you notice a leak of cerebrospinal fluid (clear fluid) through the nose. This phenomenon was observed in some patients with tumors of the pituitary gland during the treatment with bromocriptine.

Children and adolescents (aged 7 - 17 years)

Safety and effectiveness of the application of bromocriptine in children has been confirmed only in children older than 7 years with prolactinoma (pituitary tumor) and acromegaly (a disease caused by increased levels of growth hormone). There is very little data for the use of bromocriptine in children younger than 7 years. No differences were found in side effects in adults and adolescents or children, although younger children may be more sensitive to side effects. Therefore, the physician will, in children, carefully determine the dose.

Elderly

There is not enough data on clinical trials of application of bromocriptine in patients older than 65 years. Because of the frequent reduce of hepatic, renal and cardiac function, as well as presence of other disease and concomitant use of other medicines in the elderly, doctor will carefully determine the dose of bromocriptine and start the treatment with the lowest dose of bromocriptine.

Use with other medicines (Interactions)

Do not use this medicine while you are using the bromocriptine:

- antifungals (medicines for the treatment of infections caused by fungi) such as: ketoconazole, miconazole, fluconazole
- HIV protease inhibitors (medicines used to treat HIV infection) such as: ribavirin
- macrolide antibiotics such as erythromycin, josamycin
- octreotide (a medicine for the treatment of malignant diseases) in a patient with acromegaly.

These medicines increase the level of bromocriptine!

- some antipsychotic medicines (medicines used for the treatment of certain mental diseases) such as eg. phenothiazines, butyrophenones and thioxanthenes
- metoclopramide and domperidone (medicines used to treat indigestion)
These medicines may reduce the effectiveness of bromocriptine! The alcohol can reduce medicine tolerance!

### Use with food and drinks

Bromocriptine should be always taken with food. Do not use alcohol while you are on treatment with this medicine.

### Pregnancy and lactation

In patients who want to become pregnant as well as in patients in whom prove the pregnancy, the application of bromocriptine should be discontinued immediately, unless required for medical reasons to continue treatment. If you are pregnant or plan to become pregnant, you must tell your doctor to decide the other mode of treatment. Bromocriptine prevents the formation and secretion of milk, which is why it should not be given mothers who want to breastfeed. Only because of health reasons specialist can prescribe bromocriptine in nursing mothers.

### Women of childbearing age (age when women can get pregnant)

Application of bromocriptine in women can fix fertility (fertility). Women of childbearing age (age when a woman can get pregnant) who do not want to get pregnant, it is recommended the application of mechanical contraceptives.

### Driving and using machines:

In the first days of treatment with bromocriptine, since it can cause hypotension (low blood pressure), attention can be reduced, and because of that you should not drive and/or operate machines. If during the treatment with bromocriptine occurr a drowsiness and/or sudden sleep due reduced attention could be hurt or fatally injured. Therefore, you should not drive or operate machinery until you stop being somnolence and sudden sleep.

### Dosage and administration

Tablets Bromergon should always be taken with food. Tablets can be halved. The medicine should be taken exactly as your doctor has told you. The dose prescribed by your doctor depends on the disease, on your response to treatment and other medicines you are taking at the same time. It is important to follow the dosage and instructions provided by your doctor. You may not change the dose or discontinue the treatment, whereas previously without consulting your doctor. At the beginning of treatment the doctor will prescribe the lowest dose that will then gradually increased until the best effect is achieved, with the best tolerance. You should not take more than 30 mg per day, since it is a maximum allowed daily dose.

### Adults

A typical dosage: Starting dosage is 1.25 mg of bromocriptine per day, administered at evening. Your doctor will gradually increase the dose until the lowest effective dose does not achieve the
best therapeutic effects. The daily dose of every week, is gradually increased to 1.25 mg of bromocriptine per day, divided into 2 or 3 meals. Condition as a result of high levels of the hormone prolactin in the blood and reduced activity gonadal: The starting dose is 1.25 mg of bromocriptine, twice or three times a day. The dose will be gradually increased by the physician to the dose of 5-10 mg of bromocriptine per day. Preventing the formation or secretion of milk after childbirth or abortion: To prevent the creation or lactation, treatment should begin within the first few hours after childbirth or abortion, but not before the vital symptoms stabilize. On the first day of treatment, you should take with food 1.25 mg of bromocriptine at the morning and evening. Treatment is continued at a dose of 2.5 mg bromocriptine, twice daily for 14 days. Sometimes a small amount of milk can extract 2 or 3 days after treatment. In that case the treatment will be continue with the same dose of the medicine for another week. Acromegaly (a disease caused by increased levels of growth hormone) and benign (benign) tumor of the pituitary gland: The starting dose is 1.25 mg of bromocriptine, two or three times a day. Depending on the therapeutic effect and tolerability, your doctor will gradually increase the dose to 10-20 mg of bromocriptine per day. Parkinson's disease: In most patients, a typical dose is 10-30 mg per day, but in some patients larger doses may be required. In the first week of treatment, the recommended dose is 1.25 mg bromocriptine per day, administered in the evening. Your doctor will gradually increase the dose until the smallest effective dose does not achieve the best therapeutical effect. The daily dose of every week, is gradually increased to 1.25 mg of bromocriptine per day, divided into 2 or 3 meals. If in the 6 to 8 weeks of treatment does not achieve a satisfactory therapeutic effect, the dose can, every week, increase to 2.5 mg of bromocriptine daily. The patients being treated with levodopa (a medicine for the treatment of Parkinson's disease) while increasing a dose of bromocriptine should gradually reducing the dose of levodopa. In some patients, the treatment of levodopa can be completely canceled.

**Children and adolescents aged 7 to 17 years**

Pituitary tumors: In children older than 7 years, the initial dose is 1.25 mg of bromocriptine, twice or three times a day, and physician will gradually increase the number of tablets per day. For children aged 7 to 12 years maximum allowed daily dose is 5 mg, and 20 mg bromocriptine for adolescents of 13 to 17 years. Acromegaly (a disease caused by increased levels of growth hormone): In children older than 7 years, the initial dose is 1.25 mg bromocriptine, twice or three times a day. Depending on the therapeutic effect and tolerability, the doctor will gradually increase the dosage in several tablets per day. For children aged 7 to 12 years maximum allowed daily dose is 10 mg, and 20 mg bromocriptine for adolescents of 13 to 17 years.

**If you forget to take the medicine**

If you forget to take medication, do not use double dose later. Simply continue to use the medicine according to the usual schedule. If you missed medication applied, please do so as soon as possible, and then proceed with its application to the usual schedule and suitably.

**Side effects**

- Difficulty in breathing, speaking or swallowing
- Swelling of the face, lips, tongue, or throat
- Extreme drowsiness or loss of consciousness
- Skin rash, hives, or itching
- Severe headache, visual disturbances, muscle spasms similar to epileptic, very high blood
pressure, heart attack, stroke and mental disorders after childbirth or abortion.

If you notice any of the following symptoms, discontinue treatment and contact as soon as possible your doctor:

- Back pain
- Swelling of the legs
- Reduced renal function.