PACKAGE LEAFLET

Package leaflet: Information for the patient

Cabergoline Renata, tabletten 0,5 mg
cabergoline

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cabergoline Renata is and what it is used for

Cabergoline Renata contains cabergoline which belongs to a group of medicines known as prolactin inhibitors. Prolactin is a hormone that is formed in the pituitary gland of your brain. Cabergoline decreases the levels of the hormone prolactin.

Cabergoline Renata is used:
- to interrupt/inhibit lactation (milk production) for medical reasons.
- to treat hormonal disturbances as a result of high prolactin levels in female patients, such as missing or irregular periods, infertility or milk flow not associated with childbirth.
- to treat high levels of prolactin due to a tumour in the pituitary gland.

Cabergoline should only be used in adults. It is not suitable for children and adolescents under 16 years old.

You must talk to a doctor or pharmacist if you do not feel better or if you feel worse.

2. What you need to know before you take Cabergoline Renata

Do not take Cabergoline Renata if you
- are allergic to cabergoline, other ergot alkaloids (e.g., bromocriptine), or to any of the other ingredients of this medicine (listed in section 6)
- have (or have had in the past) psychosis or you are at risk of psychosis after childbirth
- have swelling of the hands and feet and a high blood pressure during pregnancy (preeclampsia, eclampsia)
- have uncontrolled high blood pressure or high blood pressure after childbirth
- have ever been diagnosed in the past with problems described as fibrotic reactions (scar tissue) affecting the lungs, back of the abdomen and kidneys or heart
- will be treated with cabergoline for a long period and have or have had fibrotic reactions (scar tissue) affecting your heart.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cabergoline Renata if you have or had any of the following conditions:

- Disease that involves the heart and blood vessels (cardiovascular disease).
- Cold hands and feet (Raynaud's syndrome).
- Gnawing pain in the abdomen when hungry (peptic ulcer) or bleeding from the stomach and intestines (gastrointestinal bleeding).
- History of serious mental disease, particularly psychotic disorders.
- Liver or kidney problems.
- Fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with cabergoline for a long period, your physician will check before starting treatment whether your heart, lungs and kidneys are in good condition. He/She will also have an echocardiogram (an ultrasound test of the heart) taken before treatment is started and at regular intervals during treatment. If fibrotic reactions occur treatment will have to be discontinued.
- Low blood pressure (postural hypotension) or you are taking any medicines to lower your blood pressure.
- Serious chest complaint (e.g., pain in the chest when breathing, fluid in the lungs, inflammation or infection of the lungs)

If you have just given birth, you may be more at risk of certain conditions. These may include high blood pressure, heart attack, convulsion, stroke or mental health problems. Therefore, your doctor will need to check your blood pressure regularly during the treatment. Speak immediately to your doctor if you experience high blood pressure, chest pain or unusually severe or persistent headache (with or without vision problems).

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings.
Your doctor may need to adjust or stop your dose.

During treatment your doctor may need to check your blood pressure, particularly in the first few days of treatment. A gynaecological assessment may also be carried out on the cells of your cervix or womb lining.

Infertility can be reversed in women taking cabergoline, and pregnancy can occur before the menstrual cycle has normalised. Therefore a pregnancy test is recommended at least every 4 weeks until menses are reinitiated, and from then on every time a menstrual period is delayed by more than 3 days. Suitable means of contraception should therefore be used during treatment and for at least one month after discontinuation of cabergoline (see section 'Pregnancy, breast-feeding and fertility').

Children and adolescents
The safety and efficacy of cabergoline has not been established in children and adolescents less than 16 years of age.

Other medicines and Cabergoline Renata
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can reduce the effectiveness of cabergoline, these include:

- Medicines to lower your blood pressure.
- Medicines used to treat mental illness (e.g. phenothiazines, butyrophenones or thioxanthenes).
- Medicines for nausea and vomiting (e.g. metoclopramide).

Some medicines can increase the side effects of cabergoline, these include:

- Medicines used in the treatment of Parkinson's disease or severe migraine headaches called ergot alkaloids, such as ergotamine or dihydroergotamine, ergometrine or methysergide.

- Antibiotics (e.g. erythromycin).

Cabergoline Renata with food and drink
This medicine should be taken with food to reduce certain side effects. Please see section 3 for details.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy
There is only limited experience of the use of cabergoline during pregnancy.
If you are planning to become pregnant, cabergoline should be discontinued at least one month before intended pregnancy. You should therefore consult your doctor if you are pregnant or plan to become pregnant before the treatment is started.
Before you can start taking cabergoline you must be checked to ensure that you are not pregnant.
Additionally, you should take care not to become pregnant during treatment and for at least one month after you have stopped treatment. Effective non-hormonal contraception should be used; discuss the choice of contraception with your doctor.
If you are being treated with cabergoline and become pregnant during this time you should discontinue the treatment and contact your doctor as soon as possible.

Breast-feeding
It is not known whether cabergoline passes into breast milk. As cabergoline will stop you from producing milk for your baby, you should not take this medicine if you plan to breastfeed. If you need to take cabergoline you should use another method for feeding your baby.

Cabergoline is used to suppress breast milk production (lactation) where it is considered essential.

Fertility
Infertility can be reversed and pregnancy can occur before the menstrual cycle has normalised in women taking cabergoline (see section 'Warnings and precautions').

Driving and using machines
Caution is required when performing actions which require fast and accurate reaction during treatment initiation.

Cabergoline can cause somnolence (extreme drowsiness) and sudden sleep onset. Persons affected by this should therefore not drive or take part in activities in which reduced alertness could incur a risk of serious harm (e.g. using machines), until such recurrent episodes and somnolence have resolved. If affected, consult your doctor.

Cabergoline Renata contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cabergoline Renata

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by your doctor who adjusts it individually for you.
The tablets should be taken by mouth and with a meal to reduce certain side effects such as nausea, vomiting and stomach pains.

- **To prevent/inhibit the production of breast milk**
  You should take 2 tablets (1 mg of cabergoline) as a single dose within 24 hours after giving birth.

- **To stop lactation once you have started breast-feeding**
  You should take 0.25 mg (one half of one 0.5 mg tablet) every 12 hours for two days.
- **To reduce the concentration of prolactin in the body**
  You should initially take 0.5 mg cabergoline per week given in one or two (one half of one 0.5 mg tablet) doses spread out over a week (e.g. half a tablet on Monday and the other half of the tablet on Thursday). Your dose will be increased up to a maximum dose of 4.5 mg per week or until you have responded fully to treatment.

The tablet can be divided into equal doses.

You should not take more than 3 mg of cabergoline in one day.

If you take more Cabergoline Renata than you should
If you take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department. Symptoms of overdose may include nausea, vomiting, gastric complaints, low blood pressure when standing, confusion/psychosis or hallucinations.

If you forget to take Cabergoline Renata
If you forget to take a dose take the next one as normal and tell your doctor if you have trouble remembering to take your tablets. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cabergoline Renata
Your doctor will advise you how long to take cabergoline. You should not stop until your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. These symptoms can be severe:
- Very common side effects (may affect more than 1 in 10 people): heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the pericardium (pericardial effusion). The early symptoms may be one or more of the following: difficulty breathing, shortness of breath, pounding heart, feeling faint, chest pain, back pain, pelvic pain or swollen legs. These may be the first signs of a condition called pulmonary fibrosis, which can affect the heart/heart valves or back.
- Development of a widespread itchy rash, difficulty breathing with or without wheezing, feeling faint, unexplained swelling of the body or tongue or any other symptoms which appear to come on rapidly after taking this medication and make you feel unwell. These may be indicative of an allergic reaction.
- Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - Aggression and altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
  - Uncontrollable excessive shopping or spending.
  - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

Other side effects that may occur are:
- **Very common (may affect more than 1 in 10 people)** feeling sick (nausea), upset stomach, stomach pain, headache, dizziness or vertigo, feeling weak or fatigued, inflammation of the stomach lining, muscle weakness.

- **Common (may affect up to 1 in 10 people)** constipation, a decrease in your blood pressure for the first 3 to 4 days after giving birth, breast pain, depression, sleep disturbances, low blood pressure (long-term treatment), low blood pressure upon standing, hot flushes, being sick (vomiting), drowsiness, tingling of fingers or toes.
- **Uncommon (may affect up to 1 in 100 people)** loss of half of the vision in one or both eyes, fainting, a tingling or 'pins and needles' sensation (digital vasospasm or paraesthesia), abnormal awareness of the beating of your heart (palpitations), decreased levels of the oxygen carrying part of your blood (haemoglobin) in women whose periods had stopped and then re-started, loss of hair, severe itching, shortness of breath, leg cramps, nosebleeds, swelling due to accumulation of fluid in the tissues (oedema), rash, skin reactions, loss of consciousness, lung scar tissue, fluid in your lungs.
- **Rare (may affect up to 1 in 1000 people)** allergic skin reactions, your fingers or toes turn white or blue with a feeling of numbness after exposure to cold.
- **Very rare (may affect up to 1 in 10,000 people)** scar tissue (fibrosis).
- **Not known (frequency cannot be estimated from the available data)** abnormal liver and abnormal blood tests of liver function, breathing problems with inadequate intake of oxygen, an increase in the level of some enzymes in the blood, abnormal vision, respiratory disorder, sudden sleep onset, seeing or hearing things that are not really there (hallucinations), delusions, psychotic disorder, allergic reaction, blood test abnormalities.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cabergoline Renata

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and on the bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25˚C. Keep the bottle tightly closed in order to protect from moisture.
- Each bottle contains 2 pcs 1g silica gel pillow pack. The silica gel packs should not be removed from the bottles after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cabergoline Renata contains
The active substance is 0.5 mg cabergoline.
The other ingredients are lactose anhydrous, l-leucine (E 641) and magnesium stearate.

What Cabergoline Renata looks like and contents of the pack
Cabergoline Renata tablets are 7.5 × 4 mm, oval-shaped, white-coloured tablets. Scored, with on one side "c" on left, "1" on right and plain on other side.

The tablets are contained in high-density polyethylene bottles with a child-resistant polypropylene cap containing silica gel pillow-packs.

Not all pack sizes may be marketed.

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In het register ingeschreven onder: RVG 131086

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Cabergoline 500 microgram Tablets
Denmark	Cabenex 0,5 mg tabletter
Spain	Cabergolina Renata 0.5 mg comprimidos
France	CABERGOLINE ZENTIVA 0,5 mg, comprimé sécable
Italy	Cabergolina Renata
Netherlands	Cabergoline Renata, tabletten 0,5 mg
Norway	Cabenex 0,5 mg tabletter
Portugal	Cabergoline Renata 0.5 mg comprimidos
Sweden	Cabenex 0,5 mg tabletter

Deze bijsluiter is voor het laatst goedgekeurd in september 2024.