

Package leaflet: Information for the patient

Cabergonicht 0.5 mg, tablets

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 Cabergonicht is and what it is used for
2. What you need to know before you take Cabergonicht
3. How to take Cabergonicht
4. Possible side effects
5. How to store Cabergonicht
6. Contents of the pack and other information

1. What Cabergonicht is and what it is used for

Cabergonicht belongs to a group of medicines known as prolactin inhibitors. Cabergonicht prevents lactation (production of milk) by decreasing levels of a hormone known as prolactin.

Cabergonicht can also be used to reduce abnormal quantities of the hormone prolactin in the blood.

2. What you need to know before you take Cabergonicht

Do not take Cabergonicht if you:

- are allergic to cabergoline or other ergot alkaloids (e.g. bromocriptine), or 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
- will be treated with Cabergonicht for a long period and *have* stiff and inflamed heart valves (cardiac valvulopathy)
- have ever been diagnosed in the past with a problem known as fibrosis affecting the lungs, lower back and kidneys or heart.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cabergonicht

If you have any of the following health problems you must inform your doctor before taking Cabergonicht as this medicine may be unsuitable for you.

- Cardiovascular disease
- Stomach ulcer or bleeding in the gastrointestinal tract. (This condition can cause black faeces or vomiting with blood)

- Impaired kidney function
- Impaired liver function
- Raynaud's disease. (When it is cold the fingers and toes become bluish white, with no pulse, cold, insensitive and fumbling).
- Low 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 a history of serious mental disorder, particularly psychotic disorders .
- In case you are treated with Cabergonicht 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.
- if you have swelling of the hands, feet and a high blood pressure during pregnancy (preeclampsia, eclampsia)
- if you have uncontrolled high blood pressure or high blood pressure after childbirth

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 behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatment.

If you have been infertile before, this can be reversed in when taking Cabergonicht, and pregnancy can occur before the menstrual cycle has normalised. Therefore a pregnancy test is recommended at least every 4 weeks until your menstrual period starts again, and from then on every time a menstrual period is delayed by more than 3 days. You should use suitable means of contraception during treatment with Cabergonicht and also at least for 4 weeks after discontinuation of treatment.

Children and adolescents

The safety and efficacy of Cabergonicht has not been established in patients less than 16 years of age.

Other medicines and Cabergonicht

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines, if taken at the same time as Cabergonicht, can interfere with the effects of your tablets. These are medicines

- for reducing blood pressure
- for the treatment of psychological illnesses such as schizophrenia or psychoses (e.g. phenothiazines, butyrophenones, thioxanthene)
- to prevent vomiting (e.g. metoclopramide)
- to treat infections (e.g. erythromycin) (concomitant use not recommended)

Cabergonicht with food, drink and alcohol

Avoid alcohol while you are taking Cabergonicht.

Pregnancy, breast-feeding and fertility

Pregnancy

Not sufficient data for the use of cabergoline during the pregnancy exists. Before you can start using cabergoline you must be checked to ensure that you are not pregnant. Additionally you should take care not to become pregnant for at least one month after you have stopped treatment with cabergoline. If you are being treated with Cabergonicht and become pregnant during this time you should contact your doctor as soon as possible.

Your doctor will then monitor your pregnancy as cabergoline can result in congenital abnormalities if you use it during pregnancy.

Breast-feeding

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

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

Fertility

Driving and using machines

Cabergonicht can reduce your ability to react quickly as it reduces blood pressure. This should be considered in cases where a high level of alertness is required, e.g. driving a car or in precision work.

Cabergonicht 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 episodes and somnolence have resolved.

Cabergonicht contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Cabergonicht

Always take this medicine exactly as your doctor 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 maximum dose is 3 mg cabergoline per day.

The tablets should be taken with meals to reduce certain side effects such as nausea, vomiting and stomach pains.

To stop/suppress the production of breast milk:

The recommended dose is 1 mg (as a single dose) within 24 hours after giving birth.

To stop lactation once you have started to breastfeed: You should take 0.25 mg (one half of Cabergonicht 0.5 mg tablet) every 12 hours for two days. This dosage regimen should not be exceeded.

To reduce the concentration of prolactin in the body:

Usually the treatment is started with 0.5 mg per week, given in one (single 0.5 mg) or two (separate 0.25 mg) doses, (e.g. half a tablet on Monday and the other half of the tablet on Thursday). The weekly dose will be gradually increased preferably by adding 0.5 mg

cabergoline per week at monthly intervals until an optimal therapeutic response is achieved. Your doctor will tell you for how long you must take your tablets.

Cabergonicht 0.5mg tablets have a score and can be divided into two equal doses.

Hepatic or renal impairment

These tablets should be used with caution.

Elderly

No dose adjustment is necessary.

Children and adolescents

Cabergonicht is not recommended in children or adolescents under 16 years of age.

If you take more Cabergonicht than you should

It is important not to take too many tablets. Contact your nearest hospital Accident and Emergency department or a doctor for advice, if you have taken too many tablets or if you think a child has swallowed any. Symptoms of overdose may include nausea, vomiting, reduced blood pressure, drop in blood pressure following a change of body position into a more upright position, stomach pain, changes in behaviour, confusion or hallucinations (seeing things), delusions. Take this leaflet and any tablets that you still have to show the doctor.

If you forget to take Cabergonicht

If you forget to take a dose at the right time, you can take it as soon as you remember it. If it is almost time to take the next dose, skip the forgotten dose and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cabergonicht

If you stop using cabergoline the symptoms of your illness may become more severe and you should discuss with your doctor before you discontinue therapy. Cabergoline takes many days to be cleared from the bloodstream and effects may worsen over a 2 week period resulting in increased lactation.

If you have any other 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 everyone gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. These symptoms can be severe:

- Heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the sac that surrounds the heart (pericardial effusion). This is a very common side effect (may affect more than 1 in 10 people). 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 lungs, heart/heart valves or lower 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.

You may experience the following side effects:

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.
- 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 behaviors; they will discuss ways of managing or reducing the symptoms.

During treatment you may also notice the following effects:

Very common (may affect more than 1 in 10 people):

Excessive daytime dizziness/vertigo*, headache*, stomach pain*, inflammation of the stomach (dyspepsia/gastritis), nausea*, weakness/lack of energy and motivation***,

Common (may affect up to 1 in 10 people):

Drowsiness/sleepiness, low blood pressure after childbirth which may not have any symptoms, drop in blood pressure following a change of body position into a more upright position, depression, hot flushes**, constipation, breast pain, vomiting**, chest pain, facial redness.

Uncommon (may affect up to 1 in 100 people):

Disorder of blood vessels (digital vasospasm), fainting, leg cramps, decrease in the value of a specific blood component (haemoglobin), a feeling of numbness or tingling, partial and transient decrease or loss of vision, abnormal heart beat, nose bleeding, fluid in the layers of the membrane lining the lungs and chest cavity, formation of scar tissue in the lung (pulmonary fibrosis), increased sexual desire, shortness of breath, swelling of tissues due to the accumulation of fluids (edema), rash, hair loss

Rare (may affect up to 1 in 1000 people):

Pain in the upper stomach

Very rare (may affect up to 1 in 10,000 people)

Formation of scar tissue of the lining of the lung (pleural fibrosis)

Not known (frequency cannot be estimated from the available data):

Aggression, , sudden sleep onset, abnormal vision, hallucinations, delusions, tremor, chest pain (angina), breathing problems (can be severe), inflammation of the lining of the lung (pleuritis), chest pain, problems with your liver , decrease in the value of specific blood components (blood creatinine phosphokinase), abnormal liver function tests

* Very common in patients treated for hyperprolactinaemic disorders; common in patients treated for inhibition/suppression of lactation

** Common in patients treated for hyperprolactinaemic disorders; uncommon in patients treated for inhibition/suppression of lactation

*** Very common in patients treated for hyperprolactinaemic disorders; uncommon in patients treated for inhibition/suppression of lactation

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 Cabergonicht

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture. The drying capsule or bag with silica gel must not be removed from the bottle.

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 Cabergonicht contains**

- The active substance is cabergoline. Each tablet contains 0.5mg cabergoline.
- The other ingredients are anhydrous lactose, L-leucin and magnesium stearate.

What Cabergonicht looks like and contents of the pack

White, oval-shaped, flat bevelled tablets containing 0,5 mg cabergoline. Each tablet is scored on one side and has "CBG" on one side and "0,5" on the other side of the break line.

Cabergonicht 0.5 mg is available in packs of 2, 4, 8, 14, 15, 16, 20, 28, 30, 32, 40, 48, 50, 60, 90, 96 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: Cabergonicht 0.5mg Tabletter.

This leaflet was last revised in 2016-11-14