**Package leaflet: Information for the patient**

**Cabergonicht 1 mg and 2 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 dopamine agonists. Cabergonicht acts in a similar way to a chemical present in the nervous system called dopamine. Patients with Parkinson's disease do not have enough of this important chemical.

Cabergonicht 1mg and 2mg is used to treat Parkinson's disease. It can be used either taken alone or in combination with levodopa, as second choice following non-ergot derived therapies.

Treatment under a specialist is required.

## 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 to any of the other ingredients of this medicine (*see Section 6 and end of Section 2*)
- have swelling of the hands, feet and a high blood pressure during pregnancy (preeclampsia, eclampsia)
- have uncontrolled high blood pressure
- will be treated with Cabergoline Teva for a long period and have or had been diagnosed in the past with a problem described as fibrotic reactions (scar tissue) affecting the lungs, back of the abdomen and kidneys or heart
- have previously experienced side effects affecting lung, such as fibrosis, associated with the use of dopamine agonists (e.g. bromocriptine, pergolide).

- have ever been diagnosed in the past with a problem known as fibrosis affecting the lungs, lower back and kidneys or heart.
    -

Before you are given Cabergonicht your doctor will arrange for you to have tests to assess the condition of your heart. Your doctor will continue to monitor your medical condition while taking Cabergonicht.

**Warnings and precautions**
**Talk to your doctor 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
- Have impaired liver function
- Have (or have had in the past) psychosis or you are at risk of psychosis after childbirth
- Raynaud's disease. (When it is cold the fingers and toes become bluish white, with no pulse, cold, insensitive and numb).
- Low blood pressure (which can result in dizziness - this usually happens on standing up)
- Serious chest complaint (e.g. pain in the chest when breathing, fluid in the lungs, inflammation or infection of the lungs)
- 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.

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.

**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)

**Cabergonicht with food, drink and alcohol**
Cabergonicht should be taken by mouth, preferably with meals.

Avoid alcohol while you are taking Cabergonicht.

**Pregnancy, breast-feeding and fertility**

*Pregnancy*

There are no adequate and well-controlled studies from the use of cabergoline in pregnant women. Animal studies have not demonstrated teratogenic effects, but reduced fertility and embryo-toxicity were observed in association with pharmacodynamic activity (see section 5.3). As there is only limited experience of the use of Cabergoline Hexal during pregnancy you should therefore consult your doctor if you are pregnant or plan to become pregnant before the treatment is started. If you are being treated with Cabergonicht and become pregnant during this time you should contact your doctor as soon as possible; he will discuss the options with you. Contraception should be continued for at least 4 weeks after stopping cabergoline.

*Fertility*

Cabergoline should only be used during pregnancy if clearly indicated and after an accurate benefit/risk evaluation. Due to the long half-life of the drug and limited data on in utero exposure, women planning to become pregnant should discontinue cabergoline one month before intended conception. If conception occurs during therapy, treatment should be discontinued as soon as pregnancy is confirmed to limit foetal exposure to the drug.

Infertility can be reversed in women taking Cabergonicht, and pregnancy can occur before the menstrual cycle has normalised. Use contraception during treatment if necessary, and continue for at least 4 weeks after stopping Cabergonicht.

*Breast-feeding*

It is not known whether cabergoline passes into breast milk. As Cabergonicht might stop you from producing enough milk for your baby, you should not breastfeed while you take Cabergonicht..

**Driving and using machines**

Cabergonicht can negatively affect the ability to react in some people and this should be considered in cases where a high level of alertness is required, e.g. driving a car and 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 recurrent episodes and somnolence have resolved. If affected, consult your doctor.

**Cabergonicht 1mg and 2mg 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 tablets should be taken with meals to reduce certain side effects such as nausea, vomiting and stomach pains.

***Adults and elderly patients***:

The dose is determined by your doctor who adjusts it individually for you. The usual dose at the start of treatment is 0.5 -1 mg cabergoline daily. The dose is then increased gradually as directed by the doctor up to a suitable maintenance dose.
The usual maintenance dose is from 2 mg up to 3 mg cabergoline daily.
The maximum dose is 3 mg cabergoline per day.

Cabergonicht 1mg and 2mg Tablets have a score and can be divided into two equal doses.

***Patients with hepatic or renal dysfunction***
These tablets should be used with caution.

***Children and adolescents***
Cabergonicht is not recommended in children and adolescents under 18 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).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 taking Cabergonicht the symptoms of your illness may become more severe and you should consult 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 worsening of symptoms of Parkinson's disease.

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 everyone gets them.

**Tell your doctor immediately** if you experience any of the following symptoms. These symptoms can be severe:

- 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, chest or back pain and swollen legs. This is a very common side effect (may affect more than 1 in 10 people).

- 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 a hypersensitivity reaction. This is an uncommon side effect (may affect up to 1 in 100 people).

**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.**

*Very common: may affect more than 1 in 10 people*
Nausea, swelling of tissues in the lower limbs due to the accumulation of fluids (peripheral edema),

*Common: may affect up to 1 in 10 people*
Vomiting, digestive disturbances, constipation, inflammation of the stomach lining (gastritis), chest pain (angina), hallucinations, confusion, sleep disturbances, somnolence, dizziness, headache, increased libido, shortness of breath, weakness/lack of energy and motivation, involuntary movements (dyskinesias), drop in blood pressure following a change of body position into a more upright position, low blood pressure after treatment for a long time, decrease in the value of specific blood components (haemoglobin, hematocrit, and/or red blood cell), abnormal liver function tests.

*Uncommon: may affect up to 1 in 100 people*
Redness, swelling and pain in the extremities of the arms and legs (erythromelalgia), excessive movements (hyperkinesia), fluid in the layers of the membrane lining the lungs and chest cavity, formation of scar tissue in the lung (pulmonary fibrosis), rash, fatigue, delusions, psychotic disorder, abnormal hepatic function, swelling of tissues due to the accumulation of fluids (edema).

*Very rare: may affect up to 1 in 10,000 people*
Formation of scar tissue (fibrosis)

*Not known: frequency cannot be estimated from the available data*
Aggression, , sudden sleep onset, fainting, hair loss, leg cramps, disorder of blood vessels (digital vasospasm), problems with the respiratory system, increased blood values of a specific enzyme called creatinine phosphokinase, , tremor, problems with your eyesight, inflammation of the lining of the lung (pleuritis), chest pain.

**Reporting of side effects**
If you get side effects , talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effect directly via [TO BE COMPLETED NATIONALLY]. 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 bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30 ºC. 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 1 mg and 2 mg cabergoline
- The other ingredients are: anhydrous lactose, L-leucin and magnesium stearate

**What Cabergonicht looks like and contents of the pack**

Cabergonicht 1 mg tablets are white, oval-shaped biconvex tablets containing 1 mg cabergoline. Each tablet is scored on both sides and has “CBG” on one side and “1” on the other side of the break line.

Cabergonicht 2 mg tablets are white, capsule-shaped, biconvex tablets. Each tablet is scored on both sides and has ‘CBG’ on one side and ‘2’ on the other side of the score line.

Cabergonicht 1 mg are available in packs of 2, 8, 14, 15, 16, 20, 28, 30, 32, 40, 48, 50, 60, 90, 96 and 100 tablets.

Cabergonicht 2 mg are available in packs of 2, 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 1mg <2 mg> Tableter

**This leaflet was last revised in 2016-11-14**