Package leaflet: Information for the user

Cabergoline Teva 1 mg tablets
Cabergoline Teva 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 Cabergoline Teva is and what it is used for

Cabergoline Teva contains the actice substance cabergoline. Cabergoline belongs to a group of medicines known as dopamine agonists.
The active substance cabergoline acts in a similar way to dopamine, a chemical substance present in the nervous system. Patients with Parkinson's disease do not have enough of this important chemical.

Cabergoline Teva is used as a second-line therapy:

- as monotherapy (without levodopa/decarboxylase inhibitors) or
- as an add-on therapy to levodopa/decarboxylase inhibitors

in Parkinson's disease if first-line therapy have failed, were not sufficient enough or were not tolerated.
Treatment and regular review of treatment under a specialist is required.
The benefit of a long-term treatment must be evaluated regularly, taking into account the risk of fibrotic reactions and valvular changes (see section 2).

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

Do not take Cabergoline Teva
- if you are allergic to cabergoline, other ergot alkaloids (e.g. bromocriptine), or any of the other ingredients of this medicine (listed in section 6),
- if you have swelling of the hands and feet and a high blood pressure during pregnancy (preeclampsia, eclampsia),
- if you have uncontrolled high blood pressure or high blood pressure after childbirth,

- if you suffer from a severe hepatic impairment,
- if you have ever been diagnosed in the past with problems described as fibrotic reactions affecting the lungs, back of the abdomen and kidneys or heart,
- if you will be treated with Cabergoline Teva for a long period and have or have had fibrotic reactions (scar tissue) affecting your heart.

Before you are given Cabergoline Teva 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 Cabergoline Teva.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cabergoline Teva.

If you have any of the following health problems Cabergoline Teva may not be suitable for you:
- Cardiovascular disease
- Severe narrowing of blood vessels in the cold with skin turning white or blue in fingers and toes (Raynaud's disease)
- Stomach ulcer or bleeding in the gastrointestinal tract (This condition can cause black faeces or vomiting with blood.)
- Impaired kidney function
- Hepatic diseases
- If you have (or have ever had) psychosis or you are at risk of psychosis after childbirth
- History of serious mental disorders, particularly psychotic disorders
- Low blood pressure, which can result in dizziness, particularly on standing up
- Serious chest complaint (e.g. pain in the chest when breathing, fluid in the lungs, inflammation or infection of the lungs)

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.

Infertility can be reversed in women taking Cabergoline Teva, 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 with Cabergoline Teva and for at least one month after discontinuation of Cabergoline Teva (see section 'Pregnancy, breastfeeding and fertility').

In long-term treatment
In case you are treated with Cabergoline Teva 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 must be discontinued.

Children and adolescents
The safety and efficacy of Cabergoline Teva have not been established in children and adolescents as Parkinson's disease does not affect this population.

Other medicines and Cabergoline Teva

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

The concomitant use of certain medicinal products and Cabergoline Teva may lead to interactions. With the following medicines interactions can be observed:

- Medicines used to lower high blood pressure
- Medicines used to treat psychological illnesses such as schizophrenia or psychoses (e.g. phenothiazines, butyrophenones, thioxanthene)
- Other ergot alkoloids and their derivatives
- Medicines used to treat vomiting (e.g. metoclopramide)
- Antibiotics (e.g. erithromycin)

To exclude interactions and determine which medicines to avoid, your treating doctor should know of such concomitant medication.

Cabergoline Teva with food, drink and alcohol
Cabergoline Teva should preferably be taken with meals to help reduce side effects.

Pregnancy, breastfeeding 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 Teva during pregnancy.
Before you can start taking Cabergoline Teva 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 with Cabergoline Teva.
Effective non-hormonal contraception should be used; discuss the choice of contraception with your doctor.
If you are being treated with Cabergoline Teva and become pregnant during this time you should discontinue the treatment and contact your doctor as soon as possible.

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

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

Driving and using machines
Cabergoline Teva 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.
You should be careful when performing actions which require fast and accurate reaction during treatment initiation.
Cabergoline Teva 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 Teva 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 Teva

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. Take your daily dose as a single dose.
Cabergoline Teva tablets can be divided into equal doses.

Adults and elderly patients
The dose is determined by your doctor who adjusts it individually for you. The recommended 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 recommended maintenance dose is from 2 mg up to 3 mg cabergoline daily.

If you take more Cabergoline Teva than you should
Contact your nearest hospital casualty department or a doctor for advice, if you have taken too many tablets or if you think a child has swallowed any. Take this leaflet and any tablets that you still have to show the doctor.

Symptoms of overdose may include nausea, vomiting, drop in blood pressure when standing up, stomach pain, changes in behaviour, confusion or hallucinations (seeing things).

If you forget to take Cabergoline Teva
If you forget to take a dose at the right time, you can take it as soon as you remember.
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 using Cabergoline Teva
If you stop using Cabergoline Teva 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 everybody gets them.

Serious side effects

Very common (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. **If you experience any of these symptoms, contact a doctor or the nearest**

hospital casualty department straight away.

Common (may affect up to 1 in 10 people)

- Pain in the chest, possibly with radiation of pain into the arm and neck and shortness of breath due to poor blood supply in the heart muscle (when concomitant use with levodopa therapy). **Contact nearest hospital casualty department straight away.**

Uncommon (may affect up to 1 in 100 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 an allergic reaction. **Contact a doctor or the nearest hospital casualty department straight away.**
- Chest pain, shortness of breath, cough and fever due to fluid in the layers of the membrane lining of the lungs and chest cavity (pleural effusion). **Contact a doctor or the nearest hospital casualty department straight away.**
- Increased shortness of breath due to formation of scar tissue in the lungs (fibrosis affecting the lungs). **Contact a doctor or the nearest hospital casualty department straight away.**

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

- Shortness of breath and cough due to formation of scar tissue in the layers of the membrane lining of the lungs and chest cavity (pleural fibrosis). **Contact a doctor or the nearest hospital casualty department straight away.**

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

- Weakened breathing, bluish lips and nails. **Contact nearest hospital casualty department straight away.**
- **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 behaviours; they will discuss ways of managing or reducing the symptoms.

<u>Other side effects</u>

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

- nausea (feeling sick)
- swelling in the legs and arms due to accumulation of fluid in the tissues (peripheral oedema)

Common (may affect up to 1 in 10 people)

- hallucinations, confusion, sleep disturbances, increased libido
- headache, somnolence (extreme drowsiness), dizziness/vertigo, involuntary movements
- low blood pressure (which can result in dizziness particularly on standing up), facial redness, hot flushes
- shortness of breath
- vomiting, indigestion, inflammation of the stomach lining (gastritis), constipation

- lack of bodily strenght/weakness
- blood problems including low blood count (symptoms may include tiredness), abnormal liver function tests

Uncommon (may affect up to 1 in 100 people)
- delusions, psychotic disorder
- excessive abnormal movements
- redness, swelling and pain in the extremities of the arms and legs (erythromelalgia)
- abnormal liver function
- skin rash
- swelling due to accumulation of fluid in the tissues (oedema), tiredness

Not known (frequency cannot be estimated from the available data)
- aggressive behaviour
- sudden sleep attacks, tremor, loss of consciousness
- visual impairment
- vasospasm (tightening in your blood vessels) in fingers and toes
- respiratory disorders and failure, inflammation and pain of the membrane surrounding the lungs (pleuritis), chest pain
- hair loss (alopecia)
- leg cramps
- increased blood values of a specific enzyme called creatinine phosphokinase

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Teva

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 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 Cabergoline Teva contains
The active substance is cabergoline.

Cabergoline Teva 1 mg tablets

Each tablet contains 1 mg cabergoline.

Cabergoline Teva 2 mg tablets
Each tablet contains 2 mg cabergoline.

The other ingredients are lactose, L-leucine and magnesium stearate.

What Cabergoline Teva looks like and contents of the pack
Cabergoline Teva 1 mg tablets are white, oval-shaped biconvex tablets with a dividing score line on both sides of the tablet. One side of the tablet is marked ‘CBG’ and ‘1’ on either side of the dividing score line.

Cabergoline Teva 2 mg tablets are white, capsule-shaped, biconvex tablets with a dividing score line on both sides of the tablet. One side of the tablet is marked ‘CBG’ and ‘2’ on either side of the dividing score line.

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

Sweden:	Cabergoline Teva 1 mg, tabletter
	Cabergoline Teva 2 mg tabletter
Germany:	Cabergolin-TEVA 1 mg Tabletten
	Cabergolin-TEVA 2 mg Tabletten

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