

Package leaflet: Information for the user

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

1. What Cabergoline Teva Pharma is and what it is used for

Cabergoline Teva Pharma belongs to a group of medicines known as dopamine agonists. Cabergoline Teva Pharma 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.

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

Treatment under a specialist is required.

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

Do not take Cabergoline Teva Pharma if you

- are allergic to cabergoline or other ergot alkaloids (e.g. bromocriptine), or to any of the other ingredients of this medicine (listed in section 6)
- have ever been diagnosed in the past with problems described as fibrotic reactions affecting the lungs, back of the abdomen and kidneys or heart
- will be treated with Cabergoline Teva Pharma for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.

Warnings and precautions

If you have any of the following health problems you **must** inform your doctor before taking Cabergoline Teva Pharma as the medicinal product 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)
- History of serious mental disorder, particularly psychotic disorders

- Impaired liver or kidney function
- If you 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
- Serious chest complaint (e.g. pain in the chest when breathing, fluid in the lungs, inflammation or infection of the lungs)
- If you have or had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabergoline Teva Pharma 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 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 Pharma, and pregnancy can occur before the menstrual cycle has normalised. Suitable means of contraception should therefore be used during treatment if necessary.

Children and adolescents

The safety and efficacy of Cabergoline Teva Pharma in children and adolescents less than 16 years of age have not been established.

Other medicines and Cabergoline Teva Pharma

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

Certain medicines used for **reducing blood pressure** and certain medicinal products (e.g. phenothiazines, butyrophenones, thioxanthene) used for the treatment of **psychological illnesses** (schizophrenia or psychoses), if taken at the same time as Cabergoline Teva Pharma **can interfere with the effects of cabergoline**. The treating doctor should therefore be aware of such concomitant medication.

There are other medicines such as other ergot alkaloids (e.g. **pergolide, bromocriptine, lisuride, ergotamine, dihydroergotamine, ergometrine or methysergide**), medicines to prevent vomiting (**metoclopramide**), and **macrolide antibiotics** (such as **erythromycin**) that may **affect the activity and tolerability** of Cabergoline Teva Pharma.

Cabergoline Teva Pharma with food and drink

Cabergoline Teva Pharma should preferably be taken with meals to help reduce the side effects.

Pregnancy and breast-feeding

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.

There is only limited experience of the use of Cabergoline Teva Pharma during pregnancy.

If you are being treated with Cabergoline Teva Pharma and become pregnant during this time you should contact your doctor as soon as possible. Contraception should be continued for at least 4 weeks after stopping cabergoline.

As Cabergoline Teva Pharma will stop you producing milk for your baby, you should not take Cabergoline Teva Pharma if you plan to breastfeed. If you need to take Cabergoline Teva Pharma you should use another method of feeding your baby.

Driving and using machines

Cabergoline Teva Pharma 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 Pharma 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. If affected, consult your doctor.

Cabergoline Teva Pharma contains lactose

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

3. How to take Cabergoline Teva Pharma

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 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.

The tablets can be divided into equal doses.

If you take more Cabergoline Teva Pharma 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, 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 Cabergoline Teva Pharma

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.

If you stop using Cabergoline Teva Pharma

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 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.

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.

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, chest or back pain and swollen legs. These may be the first signs of a condition called fibrosis, which can affect the lungs, heart/heartvalves or back. If you experience any one of these symptoms above you must tell your doctor immediately.

- Nausea, swelling in the legs and arms due to the accumulation of fluid

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

- Vomiting, indigestion, constipation, inflammation of the stomach lining (gastritis)
- Chest pain (angina pectoris) (when concomitant use with levodopa therapy)
- Hallucinations, confusion, sleep disturbances, increased libido
- Headache, somnolence (extreme drowsiness), dizziness/vertigo, involuntary movements
- Lack of bodily strength
- Low blood pressure (which can result in dizziness particularly on standing up)
- Shortness of breath
- Blood problems including low blood count (symptoms may include tiredness), abnormal liver function test

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

- Redness, swelling and pain in the extremities of the arms and legs (erythromelalgia)
- Fluid in the layers of the membrane lining the lungs and chest cavity
- Fibrotic reactions affecting the lungs
- Rash

- Swelling due to the accumulation of fluid, tiredness
- Allergic reactions (hypersensitivity)
- Delusions, psychotic disorder
- Abnormal liver function

Very rare (may affect up to 1 in 10.000 people):

- Fibrotic reactions (including fibrosis affecting the pleura)

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

- Aggression, hypersexuality, pathological gambling
- Sudden sleep attacks, fainting, tremor
- Visual impairment
- Vasospasm (tightening in your blood vessels) in fingers and toes
- Respiratory disorders and failure, pleuritis, chest pain
- Hair loss
- 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 Pharma

Keep out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original package in order to protect from moisture. The drying 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 Pharma 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 Cabergoline Teva Pharma looks like and contents of the pack

Cabergoline Teva Pharma 1 mg tablets are white, oval-shaped biconvex tablets. Each tablet is scored on both sides and has „CBG“ on one side and „1“ on the other side of the breakline.

Cabergoline Teva Pharma 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 Pharma 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.

Cabergoline Teva Pharma 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:

[To be completed nationally]

This leaflet was last revised in

2014-04-23

[To be completed nationally]