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Cabergoline 1 mg and 2 mg Tablets

cabergoline

Package leaflet: Information for the user

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

1 What Cabergoline Tablet is and what it is used for

Cabergoline belongs to a group of medicines known as dopamine agonists. Cabergoline 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 is used to treat the symptoms Parkinson's disease in adults. 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 Cabergoline Tablet

Do not take Cabergoline Tablet 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 swelling of the hands and feet and a high blood pressure during pregnancy (preeclampsia, eclampsia)
- have uncontrolled high blood pressure
- 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 for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.

Before you are given Cabergoline 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cabergoline Tablet if you have or had any of the following conditions:
- 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
- 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, 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).
- Fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabergoline for a long period, your doctor will check before starting treatment whether your heart, lungs and kidneys are in a 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) can occur following administration of this medicine, particularly during the fi rst few days. Care should be taken when taking Cabergoline with other drugs known to lower blood pressure.

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, 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 and also after discontinuation of treatment until recurrence of anovulation (see section "Pregnancy and breast-feeding").

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

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

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, 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, medicines to prevent vomiting (metoclopramide), and macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of Cabergoline.

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.

Pregnancy
You are advised to use adequate contraception while you are taking this medicine.
If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding
Tell your doctor if you are breast-feeding. You should not breast-feed while taking this medicine as this medicine may affect milk production (lactation). If you need to take Cabergoline you should use another method of feeding your baby.

Driving and using machines
Cabergoline 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.

Cabergoline can cause somnolence (extreme drowsiness) and sudden sleep onset.
Do not drive, use any tools or machines or engage in activities requiring mental alertness or coordination if you experience these symptoms until they have resolved completely. If affected, consult your doctor.

Cabergoline Tablet 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.

Tell your doctor immediately if you notice or someone notices in you:
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).

3 How to take Cabergoline Tablet

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.
Cabergoline 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 Tablet than you should
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 Tablet
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 Tablet
If you stop using Cabergoline 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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. These symptoms can be severe:
- Very common side effect (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 fibrosis, which can affect the lungs, heart/heart valves or back.
- Uncommon side effect (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.

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.

Other side effects that may occur are:

Very common (may affect more than 1 in 10 people)
- swelling of the feet and ankles due to accumulation of fluid in the tissues (oedema)
- nausea (feeling sick)

Common (may affect up to 1 in 10 people)
- vomiting, indigestion, inflammation of the stomach lining (gastritis), constipation
- chest pain (angina pectoris) (when comcomitant use with levodopa therapy)
- shortness of breath (diffi culty breathing)
- 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)
- lack of bodily strength
- blood problems including low blood count (symptoms may include tiredness), abnormal liver function tests
- decreased haemoglobin and/or red blood cells

Uncommon (may affect up to 1 in 100 people)
- redness, swelling and pain in the extremities of the arms and legs (erythromelalgia)
- excessive abnormal movements
- fluid in the layers of the membrane lining the lungs and chest cavity (pleural effusion)
- developing excess fibrous tissue in the lungs (pulmonary fibrosis)
- delusions, psychotic disorder
- skin rash
- abnormal liver function
- fatigue

Very rare (may affect up to 1 in 10,000 people)
- formation of fibrous tissues (including fibrosis affecting the pleura)

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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cabergoline Tablet

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. 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 contains
The active substance is cabergoline.

Cabergoline 1 mg tablets
Each tablet contains 1 mg cabergoline.

Cabergoline 2 mg tablets
Each tablet contains 2 mg cabergoline.
The other ingredients are: lactose, L-leucine and magnesium stearate

What Cabergoline looks like and contents of the pack
Cabergoline 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 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 is available in packs of 2, 8, 14, 15, 16, 20, 28, 30, 32, 40, 48, 50, 60, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Company responsible for manufacture: Teva Czech Industries s.r.o., Ostravska 29, indication number 305, Opava, Komarov, postal code 747 70, Czech Republic

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