Mock up

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APPROVED
By A Whitney on 07.03.2022 at

Package leaflet: Information for the user
Cabergoline 0.5mg Tablets

Your medicine is known by the above name but will be referred to as Cabergoline throughout this leaflet.
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 is and what it is used for

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

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

2. What you need to know before you take Cabergoline

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

Warnings and precautions

If you have any of the following health problems you must inform your doctor before taking Cabergoline 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
- 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) or you are taking medicines to lower blood pressure
- 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.

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").

It is recommended that women on long term treatment with Cabergoline for hormonal disorders should have regular gynaecological exams including smear tests. Your doctor will continue to monitor your medical condition while you are taking Cabergoline tablets.

Children and adolescents

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

Other medicines and Cabergoline

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, can interfere with the effects of cabergoline. The treating doctor should therefore be aware of such simultaneous 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
There is only limited experience of the use of Cabergoline during pregnancy. Before you can start taking 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 Cabergoline and become pregnant during this time you should discontinue the treatment and contact your doctor as soon as possible.

Breast-feeding

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

Nursing mothers should note that the quantity of milk can diminish.

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. 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 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

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.
Cabergoline 0.5 mg tablets can be divided into equal doses.
The tablets should be taken with meals to reduce certain side effects such as nausea, vomiting and stomach pains.
- **To stop the production of breast milk:**
  The recommended dose is 1 mg cabergoline (as a single dose) within 24 hours after giving birth.
- **To reduce the concentration of prolactin in the body:**
  Usually the treatment is started with 0.5 mg cabergoline per week, but higher doses may then be necessary. Your doctor will tell you for how long you must take your tablets.

When you first start taking the tablet, it is recommended you slowly change position when trying to sit, stand or lie down, this is because Cabergoline may cause a drop in blood pressure that could make you dizzy when you move from a position. It is also recommended that you avoid alcohol and other medicines that cause drowsiness as this could increase the risk of dizziness.
During treatment your doctor may need to check your blood pressure, particularly in the first few days of treatment. A gynaecological assessment may also be carried out on the cells of your cervix or womb lining.

If you take more Cabergoline 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

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

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 increased lactation.
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.

When used for stopping the production of breast milk approximately 14 in 100 patients have some form of side effects. The most common are low blood pressure, dizziness and headache. In treatment of increased prolactin levels side effects are more common as the tablets are taken for a longer period of time. Approximately 70 in 100 patients then experience side effects, but the side effects mostly disappear or decrease after approx. 2 weeks.

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 pericardium (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 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. 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 behaviours; they will discuss ways of managing or reducing the symptoms.

During treatment you may also notice the following side effects:

Very common (may affect more than 1 in 10 people)
- Dizziness/vertigo (a feeling of dizziness or spinning), headache
- nausea (feeling sick), indigestion, stomach pain, inflammation of the stomach lining (gastritis)
- lack of bodily strength/fatigue

Common (may affect up to 1 in 10 people)
- somnolence (extreme drowsiness)
- low blood pressure (which can result in dizziness, particularly on standing up)
- depression
- vomiting (being sick), constipation
- breast pain
- facial redness, hot flushes

Uncommon (may affect up to 1 in 100 people)
- temporary partial vision loss, loss of consciousness, crawling, tingling and or prickling sensations in the body
- nosebleeds
- leg cramps
- palpitations (feeling your heart beat)
- problems with your blood vessels in fingers and toes (vasospasm), fainting
- skin rash, hair loss
- increased libido
- swelling due to accumulation of fluid in the tissues (oedema)
- decrease in haemoglobin values in women whose periods had stopped and then re- started
- shortness of breath, fibrotic reactions (including fibrosis affecting the lungs), fluid in the layers of the membrane lining the lungs and chest cavity (pleural effusion)

Rare (may affect up to 1 in 1,000 people)
- pain in the upper central abdomen
- cramp in fingers

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)
- sudden sleep attacks, tremor
- aggressive behaviour, hallucinations, delusions, psychotic disorder
- problems with your vision
- chest pain (angina pectoris)
- abnormal liver function, abnormal liver function test
- breathing problems with inadequate intake of oxygen, inflammation and pain of the membrane surrounding the lungs (pleuritis), chest pain
- 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

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package to protect from moisture. The drying bag with silica gel must not be removed from the bottle.

If your tablets show signs of deterioration or discolouration seek the advice of your pharmacist who will tell you what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cabergoline contains

- Each tablet contains 0.5mg cabergoline.
- Also includes lactose anhydrous, L-leucine and magnesium stearate.

What Cabergoline looks like and the contents of the pack

Each oval shaped, white flat tablet with bevelled edges has a dividing score line embossed with ‘CBG’ and ‘0.5’ either side of the scoreline and is plain on the reverse.

Available in bottles containing 8 tablets.

Manufactured by Ratiopharm GmbH, DE 89079 Ulm, Germany. Procured from within the EU and repackaged by Product Licence Holder Ennogen Healthcare Ltd, Unit G4 Riverside Industrial Estate, Riverside Way, Dartford, Kent, DA1 5BS.

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