Package leaflet: Information for the patient

Cabergoline 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 is and what it is used for

Cabergoline is used to treat the symptoms of Parkinson's disease.

It is used after your doctor has tried other treatments that have not worked or for people who are already taking other medicines for this illness to help control other symptoms.

This medicine contains the active ingredient cabergoline which acts in a similar way to a chemical in the body called dopamine. Patients with Parkinson's disease do not have enough of this chemical.

Cabergoline belongs to a group of medicines called dopamine agonists.

You must talk to a doctor or pharmacist if you do not feel better or if you feel worse.

2. What you need to know before you take Cabergoline

Do not take Cabergoline
• If you are allergic (hypersensitive) to cabergoline, to other medicines called ergot alkaloids or any of the other ingredients of this medicine (listed in section 6).
• If you have swollen hands and feet and have high blood pressure.
• If you have uncontrolled high blood pressure.

• If you will be treated with Cabergoline for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.
• If you have been told you have a problem affecting your heart valves.
• If you have a previous history of respiratory or cardiac disorders linked to fibrotic tissue disorders.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cabergoline if you have or had any of the following conditions:
• Heart disease
• Raynaud's syndrome (causing cold hands and feet)
• Severe chest problems (such as pleurisy)
• Liver disease
• Stomach ulcer, or bleeding from the stomach and intestines
• Mental illness, in particular psychotic disorders
• Low blood pressure (postural hypotension) or you are taking any medicines to lower your blood pressure
• Fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabergoline for a long period, your physician will perform checks of your heart, lungs, kidneys and blood to determine if this medicine is suitable for you. 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 first 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.

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

The effectiveness of Cabergoline can be reduced by some medicines, these include:
• Medicines used to treat mental illness (e.g. phenothiazines, butyrophenones, thioxanthenes)
• Medicines used to treat sickness (e.g. metoclopramide).

Side-effects may be increased by other medicines, these include:
• Antibiotics (e.g. erythromycin)

• Drugs used for migraines (e.g. ergotamine).

Cabergoline with food and drink
Please see section 3 for details**.**

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).

Driving and using machines
Cabergoline can cause drowsiness (somnolence) and sudden sleepy episodes. 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.

Cabergoline contains lactose
Lactose is a type of sugar, if you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Cabergoline

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose of Cabergoline is 0.5 mg to 1 mg daily, preferably taken after food to reduce the side-effects. Your doctor may then increase the dose until he finds a suitable dose to control your symptoms.
You should not take more than 3 mg of this medicine in one day.

Cabergoline should be used with caution in patients with impaired liver or kidney function.

If you take more Cabergoline than you should
If too many tablets are taken by accident, contact your doctor at once or go to the nearest hospital casualty department.

If you forget to take Cabergoline
If you forget to take your medicine at the usual time, take it as soon as you remember then continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cabergoline

Your doctor will advise you how long to take Cabergoline. Your condition may return if you stop taking Cabergoline before you are advised.

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. 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: palpitations (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.
•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) Feeling sick (nausea), swelling of the feet and ankles due to accumulation of fluid in the tissues
• **Common** (may affect up to 1 in 10 people) Being sick (vomiting), indigestion, stomach pain, inflamed stomach lining, constipation, involuntary or uncontrolled movements of the limbs, hallucinations, sleep disturbances, increased sexual energy, confusion, headache, dizziness, drowsiness, suddenly falling asleep, vertigo, lack of bodily strength, weakness, chest pain (angina), abnormal blood tests for liver function, difficulty breathing, shortness of breath, low blood pressure, sudden drop in blood pressure on standing, low number of red blood cells and other blood cell changes.

• **Uncommon** (may affect up to 1 in 100 people) Severe burning pain and skin redness in the hands and feet, fatigue, delusions, psychotic disorder, accumulation of excess fluid around the lungs, scarring of the lungs, muscle spasm, excess build up of fluid in the body's tissues, abnormal liver function, rash.
• **Very rare** (may affect up to 1 in 10,000 people) Thickening of tissue covering the lungs.
• **Not known** (frequency cannot be estimated from the available data) Abnormal vision, aggressive behaviour, hair loss, leg cramps, an increase in the level of some enzymes in the blood, sudden sleep onset, fainting, tremor, hypersexuality, pathological gambling, spasm of blood vessels in fingers and toes, breathing disorders, difficulty breathing, inflammation of the lungs and chest, chest pain.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cabergoline

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

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

Cabergoline tablets absorb moisture, so you should always replace the cap after taking out your tablets.

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 contain 1 mg of cabergoline.
Cabergoline 2 mg Tablets contain 2 mg of 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 7.5 × 4 mm, oval shaped, white coloured tablets, having scored on one side 'c' on left, '2' on right and plain on other side.

Cabergoline 2 mg tablets are 10 × 5 mm, oval shaped, white coloured tablets, having scored on one side ‘c’ on left, ‘3’ on right and plain on other side.

The tablets are contained in high-density polyethylene bottles with a child-resistant polypropylene cap and silica gel pillow packs inside.

Each bottle contains 30 or 100 tablets and is enclosed in an outer cardboard carton.

Marketing Authorisation Holder
Renata Pharmaceuticals (Ireland) Limited, 13-18 City Quay, Dublin 2, Ireland.

Manufacturer
Alterno Labs d.o.o., Brnčičeva ulica 29, Ljubljana-Črnuče, 1231, Slovenia.

Distributed by:
Azure Pharmaceuticals Ltd, Blackrock, Co. Louth, Ireland.

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

Ireland	Cabergoline 1 mg & 2 mg Tablets
Germany	Cabergoletten 1 mg & 2 mg Tabletten

This leaflet was last revised in July 2023.