Package Leaflet: Information for the user

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

1. What Kabergostad is and what it is used for

Kabergostad belongs to a group of medicines known as dopamine agonists. Kabergostad 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.

Kabergostad 1mg and 2mg is used to treat Parkinson's disease. 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 Kabergostad

Do not take Kabergostad 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.
- will be treated with Kabergostad for a long period and have or had fibrotic reactions (scar tissue) affecting your heart
- have previously experienced side effects affecting lung, such as fibrosis, associated with the use of dopamine agonists (e.g. bromocriptine, pergolide).

Before you are given Kabergostad 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 Kabergostad.

Warnings and precautions
Talk to your doctor or pharmacist before taking Kabergostad if you have any of the following health problems:.

- Cardiovascular disease
- Stomach ulcer or bleeding in the gastrointestinal tract. (This condition can cause black faeces or vomiting with blood)
- Impaired kidney function
- Impaired liver function
- 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 Kabergostad 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
- History of serious mental disorder, particularly psychotic disorders.

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 Kabergostad, 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 Kabergostad has not been established in subjects less than 16 years of age.

Other medicines and Kabergostad
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicinal products.

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 Kabergostad 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), macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of Kabergostad.
.

Taking Kabergostad with food
Kabergostad should be taken by mouth, preferably with meals.

Pregnancy and breast-feeding
Pregnancy
There is only limited experience of the use of Kabergostad during pregnancy. You should therefore consult your doctor if you are pregnant or plan to become pregnant before the treatment is started. If you are being treated with Kabergostad and become pregnant during this time you should discontinue the treatment and contact your doctor as soon as possible. You should also take care not to become pregnant for at least one month once you have stopped taking Kabergostad.

Breast-feeding
As Kabergostad will stop you producing milk for your baby, you should not take Kabergostad if you plan to breast-feed. If you need to take Kabergostad you should use another method of feeding your baby.

Driving and using machines
Kabergostad 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.
Kabergostad 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.

Kabergostad 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 Kabergostad

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

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

Method of administration
Kabergostad 1mg and 2mg tablets have a score and can be divided into two equal halves.

The tablets should be taken with meals to reduce certain side effects such as nausea, vomiting and stomach pains.

If you take more Kabergostad 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 Kabergostad
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 Kabergostad
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.

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

Common (may affect up to 1 in 10 people):
Vomiting, digestive disturbances, inflammation of the stomach lining (gastritis), chest pain (angina), hallucinations, confusion, sleep disorders, somnolence (extreme drowsiness), low blood pressure (which can result in dizziness), dizziness/feeling of spinning (vertigo), headache, consitpation, increased libido, indigestion, movement disorder, general weakness, shortness of breath, abnormal liver function tests, blood test abnormalities.

Uncommon (may affect up to 1 in 100 people):
Swelling and pain in the extremities of the arms and legs (erythromelalgia), swelling due to accumulation of fluid in the tissues (oedema), rash, fatigue, abnormal blood tests of liver function, involuntary movements, delusions, psychotic disorder, allergic reaction, fluid in the layers of the membrane lining the lungs and chest cavity, lung scar tissue.

Very rare: (may affect up to 1 in 10,000 people):
*S*car tissue (fibrosis) including pleural fibrosis (a condition in which the tissue covering the lungs becomes thick and stiff).

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

Sudden sleep onset, loss of consciousness, leg cramps, loss of hair, breathing problems with inadequate intake of oxygen, inflammation of the lining surrounding the lungs which can cause pangs when breathing (pleuritis), chest pain, aggression, an increase in the level of some enzymes in the blood, a tingling or 'pins and needles' sensation (digital vasospasm) shaking (tremor), visual impairment.

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 behaviors; he or she will discuss ways of managing or reducing the symptoms.

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 {to be completed nationally: 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 Kabergostad

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 label and 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 of 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 Kabergostad 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 Kabergostad looks like and contents of the pack

Kabergostad 1 mg tablets are white, oval-shaped, biconvex, bevelled edged 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.

Kabergostad 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.

Kabergostad 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.

Kabergostad 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.>

Manufacturer: < To be completed nationally>.

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden:	Kabergostad 1mg Tablet. Kabergostad 2mg Tablet.
Germany:	Cabergolin AL 1mg Tabletten Cabergolin AL 2mg Tabletten

This leaflet was last revised in 04/2014.