

PACKAGE LEAFLET: INFORMATION FOR THE USER

Caberex 1mg and 2mg Tablets

Cabergoline

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Caberex 1 & 2mg Tablets are and what they are used for
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1. WHAT CABEREX 1 & 2MG TABLETS ARE AND WHAT THEY ARE USED FOR

Cabergoline is one of a group of medicines known as dopamine agonists. Cabergoline acts in the same way as a chemical present in the nervous system called dopamine. Patients with Parkinson's disease do not have enough of this chemical in their body. Caberex 1mg and 2mg Tablets 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. BEFORE YOU TAKE CABEREX 1 & 2MG TABLETS

Do not take Caberex 1 & 2mg Tablets if you:

- are allergic hypersensitive to cabergoline or other ergot alkaloid medicines (e.g. bromocriptine) or any of the other ingredients of Caberex 1 & 2mg Tablets.
- have swelling of the hands, feet and high blood pressure during pregnancy (pre-eclampsia, 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.
- if you will be treated with Cabergoline Tablets for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.

Take special care with Caberex 1 & 2mg Tablets

If you have any of the following health problems you must inform your doctor before taking Caberex 1 & 2mg Tablets as this medicinal product may be unsuitable for you.

- cardiovascular disease
- stomach ulcer or bleeding in the gastrointestinal tract (this can cause black faeces or vomiting with blood)
- impaired kidney function
- impaired liver function
- psychosis (currently or in the past) or if you are at risk of psychosis after childbirth

- Raynaud's syndrome (a painful condition where fingers or toes turn white, then bluish and finally red on exposure to cold or stress).
- low blood pressure
- serious chest complaints (currently or in the past) (such as difficulty in breathing)
- If you have or had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabergoline Tablets 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 Caberex 1 & 2mg Tablets, and pregnancy can occur before the menstrual cycle has normalised. Before you can start using cabergoline you have to exclude that you are pregnant. Additionally you should take care not becoming pregnant for at least one month once you have stopped treatment with cabergoline. Suitable means of contraception should therefore be used during treatment if necessary.

The safety and efficacy of Caberex 1 and 2mg Tablets have not been established in subjects less than 16 years of age.

Taking 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 Caberex 1 & 2mg Tablets can interfere with the effects of your tablets. The treating doctor should therefore be aware of all medicines you may be taking.

There are other medicines such as other ergot alkaloids, medicines to prevent vomiting (metoclopramide), medicines for reducing high blood pressure, and macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of Caberex 1 & 2mg Tablets.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicinal products, including those obtained without a prescription and natural medical products/natural products.

Taking Caberex 1 & 2mg Tablets with food and drink

Caberex 1 & 2mg Tablets should be taken by mouth, preferably with meals.

The effect of alcohol on the tolerability of cabergoline is unknown and should be avoided while you are taking Caberex 1 & 2mg Tablets.

Pregnancy and breast-feeding

Pregnancy

There is only limited experience of the use of cabergoline 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 Caberex 1 & 2mg Tablets and become pregnant during this time you should discontinue the treatment and contact your doctor as soon as possible. Contraception should be continued for at least 4 weeks after stopping Caberex 1 & 2mg Tablets.

Breast-feeding

It is not known whether cabergoline passes into breast milk. Caberex 1 & 2mg Tablets should not be taken by mothers who intend to breast feed as it prevents lactation.

Driving and using machines

Caberex 1 & 2mg Tablets can adversely 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. Caberex 1 & 2mg Tablets 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.

Important information about some of the ingredients of Caberex 1 & 2mg Tablets

Caberex 1mg and 2mg Tablets contain 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.

3. HOW TO TAKE CABEREX 1 & 2MG TABLETS

Always take Caberex 1 & 2mg Tablets exactly as your doctor has told you. You should 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 will adjust it individually for you. The usual dose at the start of treatment is 0.5 -1mg 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 2mg up to 3mg cabergoline daily. The maximum dose is 3 mg cabergoline per day.

Caberex 1mg and 2mg Tablets have a score-line and can be divided into two equal halves.

If you take more Caberex 1 & 2mg Tablets 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 Caberex 1 & 2mg Tablets

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 taking Caberex 1 & 2mg Tablets

If you stop using Caberex 1 & 2mg Tablets the symptoms of your illness may become more severe and you should discuss with your doctor before you discontinue therapy. Caberex 1 and 2mg Tablets take 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Caberex 1 & 2mg Tablets can cause side effects, although not everybody 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

The following side effects may also occur:

Very common side effects (affecting more than 1 person in 10):

Dizziness and lightheadedness on standing, involuntary/uncontrolled movements, nausea and 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. **If you experience any one of these symptoms you must tell your doctor immediately.**

Common side effects (affecting less than 1 person in 10 but more than 1 person in 100):

Vomiting, headaches, feeling tired or extreme drowsiness, digestive disturbances, inflammation of the stomach lining (gastritis), stomach pain, constipation, redness of the skin, abnormal heart beat (palpitations), chest pain (angina), depression, hallucinations, confusion, crawling/prickling sensation in the body swelling in the extremities of the arms and legs, coughing or pain when breathing, drop in red blood cells and changes in blood test results.

Uncommon side effects (affecting less than 1 person in 100 but more than 1 person in 1000):

Partial blindness (hemianopsia), nose bleeds, redness, and pain in the extremities of the arms and legs (erythromelalgia)

Rare (affecting less than one person in 1, 000 but more than one person in 10, 000): Episodes of sudden sleepiness fainting and cramp in the fingers or calves.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CABEREX 1 & 2MG TABLETS

Keep out of the reach and sight of children.

Do not use Caberex 1 & 2mg Tablets after the expiry date which is stated on the bottle after Exp. 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.

Do not remove the package containing the silica gel (desiccant) from the bottle, please refer to section 6 “Further information”.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

- The active substance is cabergoline. Each tablet contains 1mg or 2mg cabergoline.
- The other ingredients are lactose monohydrate and leucine.

What Caberex 1 & 2mg Tablets look like and contents of the pack

Caberex 1mg Tablets

A white to off-white, oval-shaped tablet, embossed with ‘C | 1’ on one side and ‘partial score >’ on the other side.

Caberex 2mg Tablets

A white to off-white, capsule-shaped tablet, embossed with ‘CE | 2’ on one side and ‘partial score >’ on the other side.

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Caberex 1 & 2mg Tablets are packed in glass bottles with a polypropylene screw cap. Within each bottle is a package which contains silica gel (desiccant) which helps protect your tablets against moisture.

Each bottle of the 1mg strength contains 20, 30, 40, 40 (2 x 20), 60, 60 (3 x 20), 90, 100 and 100 (5 x 20) tablets and each bottle of the 2mg strength contains 20, 30, 60, 60 (3 x 20), 100 and 100 (5 x 20) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Herts, SG1 4SZ, U.K.

Manufacturer:

Juta Pharma GmbH, Gutenbergstrasse 13, 24941, Flensburg, Germany

Arrow Pharma (Malta) Limited, 62 Hal Far Industrial, Estate, Birzebbugia BBG06, Malta

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