

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets are and what they are used for
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1. WHAT CABERGOLINE 0.5MG TABLETS ARE AND WHAT THEY ARE USED FOR

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

Cabergoline 0.5mg Tablets are also used to reduce abnormal quantities of the hormone prolactin in the blood.

2. BEFORE YOU TAKE CABERGOLINE 0.5MG TABLETS

Do not take Cabergoline 0.5mg Tablets

- if you are allergic (hypersensitive) to cabergoline or other ergot alkaloids medicines (e.g bromocriptine), or to any of the other ingredients of Cabergoline 0.5mg Tablets
- if you have uncontrolled high blood pressure
- if you have swelling of the hands, feet and high blood pressure during or after pregnancy (pre-eclampsia, eclampsia)
- if you have ever suffered from or are being treated for psychosis (currently or in the past) or if you are at risk of psychosis during pregnancy or after childbirth
- if you 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 0.5mg Tablets for a long period and have or had fibrotic reactions (scar tissue) affecting your heart.

Take special care with Cabergoline 0.5mg Tablets

If you have any of the following health problems you must inform your doctor before taking Cabergoline 0.5mg Tablets as the medicinal product may be unsuitable for you.

- impaired kidney function
- impaired liver function
- cardiovascular disease
- low blood pressure
- Raynaud's syndrome (a painful condition where fingers or toes turn white, then bluish and finally red on exposure to cold or stress)
- stomach ulcer or bleeding in the gastrointestinal tract (this can cause black faeces or vomiting with blood)

- if you have or had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets and pregnancy can occur before the menstrual cycle has normalized. 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 Cabergoline 0.5mg Tablets has not been established in subjects less than 16 years of age.

Before you are given Cabergoline 0.5mg Tablets 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 0.5mg Tablets.

Taking other medicines

Certain medicines used for reducing blood pressure and certain medicinal products (e.g phenothiazines, butyrophenones or thioxanthenes) used for the treatment of psychological illness (schizophrenia or psychoses), if taken at the same time as Cabergoline 0.5mg Tablets can interfere with the effects of cabergoline. 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 stop you from feeling sick (such as metoclopramide), and macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets with food and drink

Cabergoline 0.5mg Tablets should be taken by mouth, preferably with meals. This will decrease the risk of side effects like feeling sick.

The effect of alcohol on the tolerability of cabergoline is unknown and should be avoided while you are taking Cabergoline 0.5mg 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 Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets.

Infertility can be reversed in women taking Cabergoline 0.5mg Tablets and pregnancy can occur before the menstrual cycle has normalized. Suitable means of contraception should therefore be used during treatment if necessary.

Breast Feeding

You should not take Cabergoline 0.5mg Tablets if you wish to continue breastfeeding as it will affect lactation (milk production).

Ask your doctor for advice before taking any medicine.

Driving and using machines

Cabergoline 0.5mg 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.

Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets

Cabergoline 0.5mg 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 CABERGOLINE 0.5MG TABLETS

Always take Cabergoline 0.5mg 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 side effects such as nausea, vomiting and stomach pains.

Adults

The usual dose is as follows:

- To prevent lactation (production of milk):
two tablets on the first day after giving birth.
- To reduce prolactin levels in other conditions:
Treatment is started with one tablet once a week in one or two doses (e.g. half a tablet on a Monday and half a tablet on a Thursday). The dose may then be increased gradually as directed by your doctor up to a suitable maintenance dose. The usual maintenance dose is from 0.25 mg up to 2 mg per week.

If you take more Cabergoline 0.5mg 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 an overdose may include nausea, vomiting, reduced blood pressure, confusion/psychosis or hallucinations (seeing things). Take this leaflet and any tablets that you still have to show the doctor.

If you forget to take Cabergoline 0.5mg 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 Cabergoline 0.5mg Tablets

If you stop using Cabergoline 0.5mg Tablets the symptoms of your illness may become more severe and you should discuss with your doctor before you discontinue therapy. Cabergoline 0.5mg Tablets take many days to be cleared from the bloodstream and effects may worsen over a 2 week period.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cabergoline 0.5mg 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CABERGOLINE 0.5MG TABLETS

Keep out of the reach and sight of children.

Do not use Cabergoline 0.5mg 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

What Cabergoline 0.5mg Tablets contains

- The active substance is cabergoline. Each tablets contains 0.5mg cabergoline.
- The other ingredients are lactose monohydrate and leucine.

What Cabergoline 0.5mg Tablets looks like and contents of the pack

Your medicine is in the form of a tablet. The tablets are white to off-white, capsule-shaped embossed with 'C | 5' on one side and '> partial score >' on the other side.

Cabergoline 0.5mg 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 contains 2, 4, 8, 20, 28, 30, 40 & 80 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

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