Package leaflet: Information for the user
Cabergoline Aurobindo 0.5 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 Aurobindo is and what it is used for

Cabergoline Aurobindo contains cabergoline which belongs to a group of medicines known as prolactin inhibitors. Prolactin is a hormone that is formed in the pituitary gland of your brain. Cabergoline Aurobindo decreases the levels of the hormone prolactin.

Cabergoline Aurobindo is used:
- to interrupt/inhibit lactation (milk production) for medical reasons.
- to treat hormonal disturbances as a result of high prolactin levels, such as missing or irregular periods, infertility or milk flow not associated with childbirth.
- to treat high levels of prolactin due to a tumour in the pituitary gland.

2. What you need to know before you take Cabergoline Aurobindo

Do not take Cabergoline Aurobindo
- If you are allergic to cabergoline, other ergot alkaloids (e.g. bromocriptine), or to any of the other ingredients of this medicine (listed in section 6)
- If you have severe liver disease.
- If you have (or have had in the past) psychosis or you are at risk of psychosis after childbirth
- If you have swelling of the hands and feet and a high blood pressure during pregnancy (preeclampsia, eclampsia)
- If you have uncontrolled high blood pressure or high blood pressure 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 Aurobindo for a long period and have or have had fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cabergoline Aurobindo if you have or had any of the following conditions:

- 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 kidney function
- Hepatic diseases
- Severe narrowing of blood vessels in the cold with skin turning white or blue in fingers and toes (Raynaud's disease)
- Low blood pressure (which can result in dizziness, particularly on standing up)
- 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 Aurobindo 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.

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).

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 Aurobindo, 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 Aurobindo and for at least one month after discontinuation of Cabergoline Aurobindo (see section 'Pregnancy, breast-feeding and fertility').
It is recommended that women on long term treatment with Cabergoline Aurobindo for hormonal disorders should have regular gynecological exams including smear tests. Your doctor will continue to monitor your medical condition while you are taking Cabergoline Aurobindo tablets.

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

Other medicines and Cabergoline Aurobindo
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 Aurobindo 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 against vomiting (metoclopramide), and macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of Cabergoline Aurobindo.

Combined use of cabergoline and blood pressure lowering medicines may lead to a drop in blood pressure. This might impair your ability to react, therefore, it is recommended that you refrain from activities that require a high level of alertness (see 'Driving and using machines').

Pregnancy, breast-feeding and fertility
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 Aurobindo during pregnancy.

If you are planning to become pregnant, Cabergoline Aurobindo should be discontinued at least one month before intended pregnancy. You should therefore consult your doctor if you are pregnant or plan to become pregnant before the treatment is started.

Before you can start taking Cabergoline Aurobindo you must be checked to ensure that you are not pregnant.

Additionally you should take care not to become pregnant during treatment and for at least one month after you have stopped treatment with Cabergoline Aurobindo. Effective non-hormonal contraception should be used; discuss the choice of contraception with your doctor.

If you are being treated with Cabergoline Aurobindo 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 Aurobindo will stop you from producing milk for your baby, you should not take Cabergoline Aurobindo if you plan to breastfeed. If you need to take Cabergoline Aurobindo you should use another method for feeding your baby.

Fertility
Infertility can be reversed and pregnancy can occur before the menstrual cycle has normalised in women taking Cabergoline Aurobindo (see section "Warnings and precautions").

Driving and using machines
Cabergoline Aurobindo 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.
You should be careful when performing actions which require fast and accurate reaction during treatment initiation.

Cabergoline Aurobindo 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 Aurobindo 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.

3. How to take Cabergoline Aurobindo

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

It is recommended you take Cabergoline Aurobindo with or after food to help reduce feelings of nausea or vomiting.

- **To prevent/inhibit production of breast milk:**
  You should take 2 tablets (1 mg of Cabergoline Aurobindo) as a single dose within 24 hours after giving birth.
- **To stop lactation once you have started to breast-feed:**
  You should take a single dose of a ½ tablet (0.25 mg of Cabergoline Aurobindo). This dose must not be exceeded.
- **To reduce prolactin levels in other conditions:**
  Usually the treatment is started with 0.5 mg per week, but higher doses may then be necessary. Your doctor will evaluate your response to the medicine and will adjust the treatment accordingly; also he/she will tell you for how long you must take your tablets.

You should not take more than 3 mg of Cabergoline Aurobindo in one day.

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 this medicine 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 Aurobindo than you should
If you take too many Cabergoline Aurobindo tablets, contact your doctor immediately or go to the nearest hospital casualty department. Symptoms of overdose may include nausea, vomiting, gastric complaints, low blood pressure when standing, confusion/psychosis or hallucinations.

If you forget to take Cabergoline Aurobindo
If you forget to take a dose take the next one as normal and tell your doctor if you have trouble remembering to take your tablets. Do not take a double dose to make up for a forgotten dose.

If you stop using Cabergoline Aurobindo
Talk to your doctor first if you want to interrupt or stop the treatment with Cabergoline Aurobindo. If you have been treated for high levels of prolactin your symptoms will usually recur.
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 approx. 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.

Serious side effects

If you experience any of these symptoms, contact a doctor or the nearest hospital casualty department straight away.

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, pounding heart, feeling faint, chest pain, back pain, pelvic pain or swollen legs.

Uncommon (may affect up to 1 in 100 people)
- Chest pain, shortness of breath, cough and fever due to fluid in the layers of the membrane lining of the lungs and chest cavity (pleural effusion).
- Increased shortness of breath due to formation of scar tissue in the lungs (fibrosis affecting the lungs).
- 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.

Very rare (may affect up to 1 in 10,000 people)
- Shortness of breath and cough due to formation of scar tissue in the layers of the membrane lining of the lungs and chest cavity (pleural fibrosis).

Not known (frequency cannot be estimated from the available data)
- Pain in the chest, possibly with radiation of pain into the arm and neck and shortness of breath due to poor blood supply in the heart muscle.
- Weakened breathing, bluish lips and nails.
- Mental disorders (aggressive behaviour, hallucinations, delusions, psychotic disorder).
- **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)

Other 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)
- weakness, tiredness

Common (may affect up to 1 in 10 people)
- depression, sleep disturbance
- somnolence (extreme drowsiness)

- low blood pressure (which can result in dizziness, particularly on standing up), hot flush/facial redness
- vomiting (being sick), constipation
- breast pain (mastodynia)

Uncommon (may affect up to 1 in 100 people)
- increased libido
- temporary partial vision loss, loss of consciousness
- tingling and/or prickling (pins and needles) sensations in the body
- a forceful heartbeat that may be rapid or irregular
- problems with your blood vessels in fingers and toes (vasospasm)
- fainting
- shortness of breath, nosebleeds
- skin rash, hair loss
- leg cramps
- swelling due to accumulation of fluid in the tissues (oedema), swelling in feet, ankles and hands
- decrease in haemoglobin values in women whose periods had stopped and then re-started

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

Not known (frequency cannot be estimated from the available data)
- sudden sleep attacks, tremor
- problems with your vision
- breathing problems with inadequate intake of oxygen, inflammation and pain of the membrane surrounding the lungs (pleuritis), chest pain
- abnormal liver function, abnormal liver function test
- increased blood values of a specific enzyme called creatinine phosphokinase

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 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 Cabergoline Aurobindo

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 packaging after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. Do not remove the package containing the silica gel (desiccant) from the bottle.

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

6. Contents of the pack and other information

What Cabergoline Aurobindo contains

- The active substance is cabergoline. Each tablet contains 0.5 mg of cabergoline.
- The other ingredients are: leucine, lactose monohydrate and magnesium stearate

What Cabergoline Aurobindo looks like and contents of the pack
Tablet

White to off-white, capsule shaped, approximately 8mm x 4mm, flat faced, bevel edged, uncoated tablets debossed with 'C 0.5' on one side and break line on other side.
The tablet can be divided into equal doses.

Cabergoline Aurobindo tablets are available in HDPE container packs of 2 and 8 tablets.
Each HDPE container contains a desiccant sachet/canister with silica gel, which should not be swallowed.

Not all pack sizes may be marketed.

Marketing authorization holder
Aurobindo Pharma (Malta) Limited,
Vault 14, Level 2, Valleta Waterfront,
Floriana, FRN 1913,
Malta

Manufacturer:
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal
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Or

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Or

Arrow Génériques 26 avenue Tony
Garnier, Lyon, 69007,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Cabergoline AB 0,5 mg tabletten/comprimés/Tabletten
France:	Cabergoline Arrow 0,5 mg comprimé sécable
Germany:	Cabergolin PUREN 0,5 mg Tabletten
Italy:	Cabergolina Aurobindo
Malta:	Cabergoline Aurobindo 0.5 mg tablets
Netherland:	Cabergoline Aurobindo 0,5 mg tabletten
Portugal:	Cabergolina Generis

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