

APO-Cabergoline Tablets

Contains the active ingredient cabergoline

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about cabergoline. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or

- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO- Cabergoline tablets. It contains the active ingredient cabergoline.

It is used to:

- treat abnormally high levels of prolactin (hyperprolactinaemia).
- prevent the production of milk in women after birth, if breast feeding is to be prevented for medical reasons.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Cabergoline works by stimulating the receptors which inhibit the secretion of hormone known as prolactin, thus reducing your body's level of prolactin

Abnormally high prolactin may cause menstrual changes in women, impotence in men and breast changes in both sexes

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under the age of 16 years.

The safety and effectiveness in children less than 16 years of age has not been established.

Before you take this medicine

Before starting treatment with cabergoline, your doctor will need to do some tests to detect any underlying heart, lung or kidney disease. These tests include chest x-rays, physical examinations, blood tests and heart monitoring.

Your doctor will repeat these tests regularly if you are taking cabergoline for a long period of time.

While you are taking cabergoline, report anything unusual to your doctor such as difficulty in breathing, chest pain, swelling of your hands or feet, or anything else that is making you feel unwell.

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- **Any scarring or thickening of the lungs with shortness of breath**
- **Heart valve disorder**
- **Any swelling or inflammation around the heart or lungs**
- **Any abnormal formation of tissue outside the stomach wall**
- **You are hypersensitive to, or have had an allergic reaction to, cabergoline, any of the ingredients listed at the end of this leaflet or other ergot alkaloids (medicines used to treat migraines).**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - Kidney, heart and liver problems
 - Lung disease or problems with your breathing
 - Raynaud's syndrome (associated with extreme numbness, tingling and colour changes in the fingers due to cold)
 - Ulcer or bleeding in the stomach or intestines
 - Low blood pressure
 - High blood pressure after childbirth
 - History of severe mental illness
3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

It is recommended that women who plan to become pregnant stop taking cabergoline at least one month before becoming pregnant.

4. You are currently breastfeeding or you plan to breast-feed.

Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

This medicine prevents the flow of breast milk.

5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with cabergoline. These include:

- Medicines used to treat mental illness, e.g. antipsychotic medicines for schizophrenia
- Medicines used to treat high blood pressure
- Ergot alkaloids, medicines used to treat migraine

- Medicines used to prevent nausea and vomiting (e.g. metoclopramide)
- Medicines called macrolide antibiotics which are used to treat bacterial infections (e.g. erythromycin)

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with cabergoline.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

To treat high levels of prolactin (hyperprolactinaemia), the recommended starting dose is 250 micrograms (half a 500 microgram tablet) taken twice a week. Your doctor will generally start you on a low dose and may gradually increase your dose.

To prevent the production of breast milk, the recommended dose is 1mg (two 500 microgram tablets) taken once, on the first day after delivery of your baby.

How to take it

Swallow cabergoline tablets with a glass of water.

When to take it

Take this medicine on the same day each week. Taking it on the same day each week will have the best effect and will also help you remember when to take it.

Take your medicine with food or a meal.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of taking too much cabergoline may include nausea, vomiting, stomach pains and dizziness.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

- Use barrier methods of contraception, such as condoms, to prevent pregnancy during and for at least one month after taking cabergoline.
- Your doctor may recommend routine pregnancy tests during long periods of treatment.
- Stop taking cabergoline immediately if you become pregnant and consult your doctor.
- Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. These tests may include chest x-rays, physical examinations, blood tests and heart monitoring.
- Follow your doctor's requests for tests and report anything unusual to your doctor such as difficulty in breathing, chest pain or swelling of your hands or feet.
- Keep all your doctor's appointments while taking cabergoline so that your progress can be checked.
- Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.

- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Cabergoline may cause dizziness or affect your ability to respond quickly.

If you feel sleepy while taking cabergoline, do not drive or operate machinery.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

See your doctor if you notice changes in your behaviour that result in a strong desire to either gamble, shop, eat or use medicines to excess, or you notice an increase in your sex drive.

Such compulsive behaviours have been seen with this class of medicine, including cabergoline.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking cabergoline or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side

effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- Dizziness, fainting
- Headache
- Nausea or vomiting
- Unusual sleepiness
- Abdominal pain or heartburn or pain in the stomach
- Constipation
- Nosebleed
- Weakness or tiredness
- Temporary impairment of vision
- Breast pain
- Hot flushes
- Rash
- Hair loss

These side effects listed above are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- Irregular heart beat
- Leg cramps or pain in the fingers or toes
- Aggressive behaviour
- Depression, feelings of deep sadness
- Changes in behaviour such as increased sex drive, a compelling desire to gamble, shop, eat or take medicines
- Any breathing problems

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- Chest pain
- Sudden signs of allergy (see Allergic reactions section below)
- Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking cabergoline.

- Other side effects not listed above may occur in some patients.
- Some of these side effects (e.g. changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

Allergic reactions

If you think you are having an allergic reaction to cabergoline, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect from heat, light and moisture.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO- Cabergoline Tablets looks like

0.5mg tablets: white coloured, capsule shaped, flat, scored tablet, embossed "APO" on one side and "CA" bisect '0.5" on the other side

Bottles of 2 and 8 tablets.

* Not all pack sizes may be available.

Ingredients

Each tablet contains 500 micrograms of cabergoline as the active ingredient.

It also contains the following inactive ingredients:

- lactose anhydrous
- magnesium stearate

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Cabergoline 500 microgram tablets : AUST R 218126.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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