

DOSTINEX®

Cabergoline 500 microgram

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Dostinex against the expected benefits.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Dostinex is used for

Dostinex may be prescribed by your doctor to reduce your body's level of a hormone known as prolactin. Dostinex may be needed if your levels of prolactin are abnormally high (hyperprolactinaemia).

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

Dostinex can also be prescribed to prevent the production of milk in women after birth, if breastfeeding 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 it for another reason.

Dostinex is available only with a doctor's prescription.

Before you start to take Dostinex

Before starting treatment with Dostinex, 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 Dostinex for a long period of time.

While you are taking Dostinex 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 Dostinex if you have an allergy to:

- any medicine containing cabergoline
- any of the ingredients listed at the end of this leaflet
- ergot alkaloids (medicines used to treat migraine).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Dostinex if you have or have had:

- 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.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not give this medicine to a child under the age of 16 years.

The safety and effectiveness in children has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have or have had any of the following medical conditions:

- 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.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved. It is recommended that women who plan

to become pregnant stop taking Dostinex at least one month before becoming pregnant.

Tell your doctor if you are breastfeeding or intend to breastfeed.

This medicine prevents the flow of breast milk.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take Dostinex.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Dostinex may interfere with each other. 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).

These medicines may be affected by Dostinex or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Dostinex.

How to take Dostinex

Follow all directions given to you by your doctor or pharmacist carefully.

The directions given to you by your doctor or pharmacist on how to take

Dostinex may differ from the information contained in this leaflet. You may be given a different dosage depending on your condition or how you react to the medicine.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

To treat high levels of prolactin (hyperprolactinaemia), the recommended starting dose is half a 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 two tablets taken as a single dose, on the first day after delivery of your baby.

How to take it

Swallow Dostinex tablets with a glass of water.

When to take it

Take your medicine with food or a meal.

How long to take it

Continue taking Dostinex until your doctor tells you to stop.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking your medicine as you normally would.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, speak to your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice (in Australia telephone 13 11 26, in New Zealand telephone 0800 POISON or 0800 764 766) or go to the Accident and Emergency department (Casualty) at your nearest hospital if you think you or anyone else may have taken too much Dostinex. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers for these services handy. Have the medicine or this leaflet available to give details if needed.

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

While you are taking Dostinex

Things you must do

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 of your doctor's appointments while taking Dostinex so that your progress can be checked.

It is important that your doctor carries out some regular tests if you are taking Dostinex for a long period of time to make sure the medicine is working and to prevent unwanted side effects. These tests may include chest x-rays, physical examinations, blood tests and heart monitoring.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Dostinex.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Use barrier methods of contraception, such as condoms, to

prevent pregnancy during and for at least one month after taking Dostinex.

Your doctor may recommend routine pregnancy tests during long periods of treatment.

Stop taking Dostinex immediately if you become pregnant and consult your doctor.

Things you must not do

Do not use Dostinex to treat any other medical complaints unless your doctor tells you to.

Do not stop taking your medicine until your doctor tells you to, even if you are feeling better.

Do not give Dostinex to anyone else, even if they have the same condition as you.

Things to be careful of

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

Be careful driving or operating machinery until you know how Dostinex affects you.

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

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

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.

Side effects

Tell your doctor as soon as possible if you do not feel well while taking Dostinex, even if you do not think the problems are connected with the medicine or they are not listed in this leaflet.

Like many medicines, Dostinex may cause side effects. If they occur, they are likely to be minor and temporary.

However, some may be serious and need medical attention.

It can be difficult to tell whether side effects are the result of taking Dostinex, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist about any questions you may have.

Tell your doctor if...

Tell your doctor if you notice any of the following and they worry you:

- 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.

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

Tell your doctor as soon as possible if...

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

- 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.

The above list includes serious side effects, which may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- chest pain with shortness of breath
- sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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 Dostinex.

Other side effects not listed above may also 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.

After taking Dostinex

Storage

Keep Dostinex in its container until it is time to take it.

Keep Dostinex in a cool dry place, where the temperature stays below 25°C.

Do not store Dostinex, or any medicines, in a bathroom or near the sink. Do not leave Dostinex in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Dostinex 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

Ask your pharmacist what to do with any Dostinex which is left over, or if the medicine has passed its expiry date.

Australian Registration Number

AUST R 52158

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Product Description

What it looks like

Dostinex comes as capsule-shaped, flat, white tablets. One side is marked with the letter 'P' on a side of the score and the letter 'U' on the other.

The other side of the tablet is marked '700' with a short score on the top and bottom of the tablet surface.

Dostinex is available in amber glass bottles of 2 and 8 tablets.

Ingredients

Active Ingredient

The active ingredient is cabergoline 500 microgram.

Inactive Ingredients

Each tablet also contains: lactose and leucine.

Supplier

Dostinex tablets are supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia
Toll Free number: 1800 675 229

Dostinex tablets are supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand
Toll free number: 0800 736 363