

Dostinex®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Dostinex?

Dostinex contains the active ingredient cabergoline. Dostinex may be needed if your levels of a hormone known as prolactin are abnormally high (hyperprolactinaemia). Dostinex can also be prescribed to prevent the production of milk in women after birth. For more information, see Section [1. Why am I using Dostinex?](#) in the full CMI.

2. What should I know before I use Dostinex?

Before starting treatment your doctor will need to do some tests to detect any underlying heart, lung or kidney disease. Do not take 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; or any abnormal formation of tissue outside the stomach wall.

Do not take if you have an allergy to any medicine containing cabergoline, ergot alkaloids or any of the ingredients listed. For more information, see Section [2. What should I know before I use Dostinex?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with cabergoline and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Dostinex?

To treat 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. More instructions can be found in Section [4. How do I use Dostinex?](#) in the full CMI.

5. What should I know while using Dostinex?

| Things you should do | |
|----------------------|---|
| | <ul style="list-style-type: none">• Follow your doctor's requests for tests and report anything unusual |

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|---------------------------------|--|
| | <p>to your doctor such as difficulty in breathing, chest pain or swelling of your hands or feet.</p> <ul style="list-style-type: none"> • Keep all of your doctor's appointments so that your progress can be checked. • 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 to prevent pregnancy during and for at least one month after taking Dostinex. • Stop taking Dostinex immediately if you become pregnant and consult your doctor. |
| Things you should not do | <ul style="list-style-type: none"> • Do not use Dostinex to treat any other medical |

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| | <p>complaints unless your doctor tells you to.</p> <ul style="list-style-type: none"> • 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. |
| Driving or using machines | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Dostinex affects you. |
| Looking after your medicine | <ul style="list-style-type: none"> • 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. |

For more information, see Section [5. What should I know while using Dostinex?](#) in the full CMI.

6. Are there any side effects?

Some common side effects include 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 or hair loss. For more serious side effects and further information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Dostinex[®] (doss-tee-nex)

Active ingredient(s): cabergoline (ca-ber-go-lean)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dostinex. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dostinex.**

Where to find information in this leaflet:

1. Why am I using Dostinex?
2. What should I know before I use Dostinex?
3. What if I am taking other medicines?
4. How do I use Dostinex?
5. What should I know while using Dostinex?
6. Are there any side effects?
7. Product details

1. Why am I using Dostinex?

Dostinex contains the active ingredient cabergoline.

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 breast-feeding is to be prevented for medical reasons.

2. What should I know before I use Dostinex?

Warnings

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.

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.
- an allergy to any medicine containing cabergoline, ergot alkaloids (medicines used to treat migraine) or any of the ingredients listed at the end of this leaflet. 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 give this medicine to a child under the age of 16 years.

The safety and effectiveness in children have not been established.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - kidney, heart or 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.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Your doctor will 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 plan to breastfeed.

This medicine prevents the flow of breast milk.

3. What if I am taking other medicines?

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

Some medicines may be affected by Dostinex or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- 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).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dostinex.

4. How do I use Dostinex?

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.

Follow all instructions from your doctor and pharmacist carefully.

How to take it

Swallow Dostinex tablets with a glass of water.

When to take Dostinex

Take your medicine with food or a meal.

Taking it with food will lessen any side effects you may experience.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you are not sure of how to take Dostinex, ask your doctor or pharmacist.

How long to take it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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, ask your doctor or pharmacist.

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

If you take too much Dostinex

If you think that you have taken too much Dostinex, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include:

- nausea
- vomiting
- stomach pains
- dizziness.

Have the Dostinex bottle or box or this leaflet available to give details if needed.

5. What should I know while using Dostinex?

Things you should 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.

Tell your doctor as soon as possible if you notice an increase in your blood pressure, or you experience severe headache that is getting progressively worse (with or without changes in vision); you may need medical attention.

Call your doctor right away or go straight to the Emergency Department at your nearest hospital if you experience seizures, sudden chest pain that does not go away with rest, or stroke symptoms (including trouble walking, speaking and understanding, as well as numbness of the face, arm or leg on one side of the body).

Keep all of your doctor's appointments 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 should not do

Do not use Dostinex to treat any other 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.

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 medicines, including cabergoline.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

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

If you take the tablets out of the bottle they may not keep well.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep Dostinex where young children cannot reach it.

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

| Side effects | What to do |
|--|---|
| <ul style="list-style-type: none"> • 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 | <p>Speak to your doctor if you have any of these common side effects and they worry you.</p> |
| <ul style="list-style-type: none"> • irregular heartbeat • leg cramps or pain in the fingers or toes • aggressive behaviour • depression, feelings of deep sadness • change in behaviour such as increased sex | <p>Tell your doctor as soon as possible. You may require medical attention.</p> |

| Side effects | What to do |
|--|--|
| <p>drive, a compelling desire to gamble, shop, eat or take medicines</p> <ul style="list-style-type: none"> • any breathing problems • increase in your blood pressure, or you experience severe headache that is getting progressively worse (with or without changes in vision) | |
| <ul style="list-style-type: none"> • seizures • sudden chest pain that does not go away with rest • stroke symptoms (including trouble walking, speaking and understanding, as well as numbness of the face, arm or leg on one side of the body) • 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, | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention or hospitalisation.</p> |

| Side effects | What to do |
|---|------------|
| shortness of breath, wheezing or difficulty breathing | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Dostinex contains

| | |
|---|---|
| Active ingredient (main ingredient) | cabergoline 500 microgram per tablet |
| Other ingredients (inactive ingredients) | leucine |
| Potential allergens | Sugars (as lactose) |

Do not take this medicine if you are allergic to any of these ingredients.

What Dostinex 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.

AUST R 52158

Dostinex is available in bottles of 2 and 8 tablets.

Who distributes Dostinex

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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