Package leaflet: Information for the patient

Dostinex® 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

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1. What Dostinex is and what it is used for
- Dostinex contains the active ingredient cabergoline. This medicine belongs to a class of medicines called 'dopamine agonists'. Dopamine is produced naturally in the body and helps to transmit messages to the brain.
- Dostinex is used to stop breast milk production (lactation) soon after childbirth, stillbirth, abortion or miscarriage. It can also be used if you do not want to continue to breast-feed your baby once you have started.
- Dostinex can also be used to treat other conditions caused by hormonal disturbance which can result in high levels of prolactin being produced. This includes lack of periods, infrequent and very light menstruation, periods in which ovulation does not occur and secretion of milk from your breast without breast-feeding. Also in conditions in which high levels of prolactin are due to unknown causes (idiopathic hyperprolactinaemia) or are caused by tumours of the pituitary gland in both men and women.
- Cabergoline mimics the action of dopamine to reduce the production of prolactin in the blood. Prolactin is the hormone which stimulates the breast to produce milk.
- Dostinex should only be used in adults. It is not suitable for children under the age of 16 years.
- You must talk to a doctor or pharmacist if you do not feel better or if you feel worse.

2. What you need to know before you take Dostinex
Do not take Dostinex:
- If you are allergic to cabergoline, to other medicines called ergot alkaloids, (e.g. pergolide, bromocriptine, lisuride, ergotamine or ergometrine) or to any of the other ingredients of this medicine (listed in section 6)
- If you have severe liver disease
- If you have high blood pressure in pregnancy associated with swelling and protein in the urine (toxaemia of pregnancy)
- If you are being treated with anti-psychotics or have a history of mental illness associated with child-birth (puerperal psychosis)
- If you are pregnant or breast-feeding
- If you will be treated with Dostinex for a long period and have stiff and inflamed heart valves (cardiac valvulopathy)
- If you have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs.

Warnings and precautions
Talk to your doctor or pharmacist before taking Dostinex if you have or had any of the following conditions:
- Disease that involves the heart and blood vessels (cardiovascular disease)
- Cold hands and feet (Raynaud's syndrome)
- Gnawing pain in the abdomen when hungry (peptic ulcer) or bleeding from the stomach and intestines (gastrointestinal bleeding)
- History of serious mental disease, particularly psychotic disorders
- Reduced liver function
- Kidney function abnormality or kidney disease
- Increased blood pressure after giving birth
- Fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen. In case you are treated with Dostinex for a long period, your physician will check before starting treatment whether your heart, lungs and kidneys are in good condition. They 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
- Low blood pressure (postural hypotension) or you are taking any medicines to lower your blood pressure.

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.
It is recommended that women on long term treatment with Dostinex for hormonal disorders should have regular gynaecological exams including smear tests. Your doctor will continue to monitor your medical condition while you are taking Dostinex tablets.

Other medicines and Dostinex
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can reduce the effectiveness of Dostinex, these include:
- Medicines used to treat mental illness (e.g. antipsychotic medicines like chlorpromazine, haloperidol)
- Medicines for nausea and vomiting (e.g. domperidone, metoclopramide)

Some medicines can increase the amount of Dostinex in your blood and so could increase the side effects, these include:
- Medicines for Parkinson's disease
- Medicines for severe migraine headaches (e.g. pergolide, bromocriptine, lisuride, ergotamine, dihydroergotamine, ergometrine or methysergide)
- Antibiotics (e.g. erythromycin).

Dostinex with food and drink
See section 3 'How to take Dostinex'.

Pregnancy, breast-feeding and fertility
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should also take care not to become pregnant for at least one month once you have stopped taking this medicine. If you become pregnant during treatment with Dostinex, stop taking Dostinex and inform your doctor who will then monitor your pregnancy as Dostinex can result in congenital abnormalities if you use it during pregnancy.

Breast-feeding
As Dostinex will stop you producing milk for your baby, you should not take this medicine if you plan to breast-feed. If you need to take Dostinex you should use another method of feeding your baby.

Driving and using machines
Dostinex can cause drowsiness (somnolence) and sudden sleepy episodes, in some cases without any warning signs or awareness. You are advised not to drive or operate machines or engage in activities requiring mental alertness or coordination during treatment with this medicine. Your doctor will decide if you can continue treatment on Dostinex if this occurs.

Dostinex contains lactose
Lactose is a type of sugar, if you have been told you have an intolerance to sugars, consult your doctor before you take this medicine.

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

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

- **To prevent milk production (lactation)**: You should take 1 mg (two 0.5 mg tablets) on the first day after delivery.
- **To stop lactation once you have started to breast-feed**: You should take 0.25 mg (one half of Dostinex 0.5 mg tablet) every 12 hours for two days.
- **To reduce prolactin levels in other conditions**: You should initially take one 0.5 mg tablet (to be taken in two doses) spread out over a week (e.g. half a tablet on Monday and the other half of the tablet on Thursday). Your dose will be increased up to a maximum dose of 4.5 mg per week or until you have responded fully to treatment. The maximum dose should not exceed 3 mg per 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 Dostinex than you should
If you take too many Dostinex 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 Dostinex
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 taking Dostinex
Your doctor will advise you how long to take Dostinex. You should not stop until your doctor tells you.

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.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. These symptoms can be severe:
- Abnormal or unusual thoughts.
- Heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the pericardium (pericardial effusion). This is a very common side effect (may affect more than 1 in 10 people). 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. These may be the first signs of a condition called pulmonary fibrosis, which can affect the lungs, heart/heart valves or lower back.
- 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.

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.
  - Aggression and 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.

During treatment you may also notice the following effects:
- **Very common: may affect more than 1 in 10 people:** drowsiness, nausea, headache, dizziness, vertigo, stomach pain, indigestion, inflamed stomach lining, fatigue, lack of bodily strength, weakness.
- **Common: may affect up to 1 in 10 people:** constipation, blurred vision, low blood pressure after childbirth which may not have any symptoms, breast pain, depression, sleep disturbances, excessive daytime drowsiness/sleepiness, vomiting, low blood pressure, hot flushes.
- **Uncommon: may affect up to 1 in 100 people:** loss of hair, severe itching, hypersensitivity reaction, shortness of breath, fainting, nosebleed, leg cramps, swelling due to accumulation of fluid in the tissues (oedema), rash, irregular or strong heartbeat (palpitations), pins and needles sensation, decrease in haemoglobin in women whose periods had stopped and then re-started, temporary partial vision loss, cold hands and feet.
- **Rare: may affect up to 1 in 1000 people:** pain in the stomach.
- **Not known: frequency cannot be estimated from the available data:** abnormal liver and abnormal blood tests of liver function, breathing problems with inadequate intake of oxygen, chest pain, tremor, an increase in the level of some enzymes in the blood, abnormal vision, episodes of sudden sleep onset, seeing or hearing things that are not really there (hallucinations), delusions, psychotic disorder.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme website:
www.mhra.gov.uk/yellowcard

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Dostinex
- 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 carton and on the bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Keep the bottle tightly closed in order to protect from moisture.
- The bottle caps contain desiccant granules. Do not remove desiccant granules from cap or transfer tablets to another container.

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

6. Contents of the pack and other information
What Dostinex contains
The active substance is cabergoline. Each tablet contains 0.5 mg of cabergoline.
The other ingredients are lactose and leucine (see section 2 **Dostinex contains lactose**).

What Dostinex looks like and contents of the pack
Dostinex tablets are flat capsule-shaped, scored, white tablets. The tablets are contained in either amber glass bottles, stoppered with an aluminium tamper-evident screw cap with silica gel insert, or high-density polyethylene bottles with a child-resistant polypropylene cap which has a desiccant canister containing silica gel. Each bottle contains 2, 4 or 8 tablets and is enclosed in an outer cardboard carton.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder	Pfizer Limited Ramsgate Road Sandwich, Kent CT13 9NJ
Manufacturer	Pharmacia Italia Marino Del Tronto Ascoli, Piceno Italy

Company Contact Address
For any further information about this medicine, please contact Medical Information at: Pfizer Limited, Walton Oaks, Tadworth, Surrey, KT20 7NS. Tel: 01304 616161

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