Package leaflet: Information for the patient

Dostinex® 500 microgram 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

- This medicine contains cabergoline and belongs to a class of medicines called 'dopamine agonists'. Dopamine is produced naturally in the body and helps to transmit messages to the brain.
- 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 is used to suppress breast milk production (lactation) where it is considered essential, but should not be used for routine suppression of lactation, or the relief of symptoms of postpartum pain and engorgement, which can be adequately treated with simple analgesics and breast support.
- Dostinex can also be used to treat conditions caused by hormonal disturbance which can result in high levels of prolactin being produced. This includes high levels of prolactin caused by tumours of the pituitary gland in both men and women, missing or irregular periods, infertility, milk secretion (for women).
- 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 or had fibrotic reactions (scar tissue) affecting the valves of your heart.
- If you have a history of fibrotic reactions (scar tissue) affecting your heart, lungs or abdomen.

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.
- Liver or kidney problems.
- 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. 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.
- Low blood pressure (postural hypotension) or you are taking any medicines to lower your blood pressure.

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.

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 to lower your blood pressure.
- Medicines used to treat mental illness (e.g. phenothiazines, butyrophenones or thioxanthenes).
- Medicines for nausea and vomiting (e.g. metoclopramide).

Some medicines can increase the side effects of Dostinex, these include:
- Medicines used in the treatment of Parkinson's disease or severe migraine headaches called ergot alkaloids, such as ergotamine or dihydroergotamine, ergometrine or methysergide.

- Antibiotics (e.g. erythromycin).

Dostinex with food and drink
Please see section 3 for details.

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. 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
As Dostinex can cause drowsiness (somnolence) and sudden sleepy episodes, you are advised not to drive or operate machines or engage in activities requiring mental alertness or coordination during treatment with this medicine.

Dostinex 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 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 1mg (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 one Dostinex 0.5 mg tablet) every 12 hours for two days.
- **To reduce prolactin levels in other conditions**: You should initially take 0.5 mg Dostinex per week given in one or two (one half of one 0.5 mg tablet) 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.

You should not take more than 3 mg of Dostinex 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 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:

- Very common side effects (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. These may be the first signs of a condition called pulmonary fibrosis, which can affect the heart/heart valves or 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.
- 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.

Other side effects that may occur are:

- **Very common (may affect more than 1 in 10 people)** feeling sick (nausea), upset stomach, stomach pain, headache, dizziness or vertigo, feeling weak or fatigued, inflammation of the stomach lining, muscle weakness.
- **Common (may affect up to 1 in 10 people)** constipation, a decrease in your blood pressure for the first 3 to 4 days after giving birth, breast pain, depression, sleep disturbances, low blood pressure (long-term treatment), low blood pressure upon standing, hot flushes, being sick (vomiting), drowsiness, tingling of fingers or toes.

- **Uncommon (may affect up to 1 in 100 people)** loss of half of the vision in one or both eyes, fainting, a tingling or 'pins and needles' sensation (digital vasospasm or paraesthesia), abnormal awareness of the beating of your heart (palpitations), decreased levels of the oxygen carrying part of your blood (haemoglobin) in women whose periods had stopped and then re-started, loss of hair, severe itching, shortness of breath, leg cramps, nosebleeds, swelling due to accumulation of fluid in the tissues (oedema), rash, skin reactions, loss of consciousness, lung scar tissue, fluid in your lungs.
- **Rare (may affect up to 1 in 1000 people):** allergic skin reactions, your fingers or toes turn white or blue with a feeling of numbness after exposure to cold.
- **Very rare (may affect up to 1 in 10,000 people)** scar tissue (fibrosis).
- **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, an increase in the level of some enzymes in the blood, abnormal vision, respiratory disorder, sudden sleep onset, seeing or hearing things that are not really there (hallucinations), delusions, psychotic disorder, allergic reaction, blood test abnormalities.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Ireland
HPRA Pharmacovigilance. Website: www.hpra.ieBy reporting side effects you can help provide more information on the safety of this medicine.

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 your 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 500 microgram cabergoline.
The other ingredients are lactose anhydrous (see section 2 Dostinex contains lactose) and leucine.

What Dostinex looks like and contents of the pack

Dostinex is a flat capsule-shaped, scored, white tablet. The tablets are contained in either amber glass bottles, stoppered with an aluminum 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

Ireland Product Authorisation holder Pfizer Healthcare Ireland,
9 Riverwalk, National Digital Park,
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Dublin 24, Ireland

Malta Product Authorisation holder Pfizer Hellas S.A.
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Manufacturer: Pfizer Italia S.r.l
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Company Contact Address
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