DOSTINEX®

Cabergoline

0.5 mg tablets

Reference Market: Italy

PACKAGE LEAFLET

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

1. What Dostinex is and what it is used for

Dostinex contains the active substance cabergoline, which belongs to a group of medicines called prolactin inhibitors (prolactin is a hormone that stimulates the production of milk from the breasts). Cabergoline works by reducing the production of prolactin in the blood.

1. Dostinex is used **immediately after** birth to prevent the normal production and secretion of breast milk (lactation), or to interrupt lactation that has already started:
   - when you do not want to continue to breastfeed your baby;
   - when breastfeeding is not recommended for reasons of health of the mother or the new-born;
   - after the birth of a foetus dead in utero;
   - after an abortion or miscarriage.

2. Dostinex may also be used to treat other conditions that may be caused by high levels of prolactin (hyperprolactinaemia), such as:
   - the absence or disappearance of menstruation (amenorrhoea);
   - menstrual cycle changes (oligomenorrhoea);
   - suspension or termination of ovulation (anovulation);
   - persistent production of breast milk after the cessation of breastfeeding (galactorrhea).

   High prolactin levels are caused by some types of pituitary disease (a gland located at the base of the skull) in both men and women.

2. What you need to know before you take Dostinex

Do not take Dostinex:
- if you are allergic to cabergoline, to similar medicines called ergot alkaloids, or any of the other ingredients of this medicine (listed in section 6).
- If you have ever had fibrotic reactions (scar tissue formation) that affected the lungs, heart or abdomen.
- For a long period of time if you have ever had or you have a heart valves disorder, including cases of fibrotic reactions (scar tissue formation) involving the heart valves.

Warnings and precautions
Tell your doctor or pharmacist if you have or have ever suffered from any of these conditions:

- Severe disorders of the heart or blood vessels (veins and/or arteries);
- A disease that causes cold hands and feet (Raynaud's syndrome);
- Stomach ulcers;
- Bleeding from the stomach or intestine;
- Severe mental illness, particularly psychotic disorders (severe mental equilibrium alterations);
- If you have very poor liver function (severe liver failure) and have already been treated with this medicine for a long time, because this situation may require a lower dose of Dostinex expected;
- If you have high blood pressure (hypertension) and are already taking other medicines to lower it. Use particular caution when taking Dostinex with other medicines that lower blood pressure because you may experience a drop in blood pressure after taking Dostinex when moving from a sitting or lying position to a standing position. Dostinex can also lower blood pressure when taken for a long period of time;
- High blood pressure (hypertension) which suddenly occurs during pregnancy or shortly after delivery, because treatment with Dostinex may not be suitable for you. The doctor will assess the risks and benefits of administering this medicine according to your conditions.

If you have just given birth, you may be at risk of developing certain conditions. These may include hypertension, infarction, seizures, stroke or psychiatric disorders. Your doctor will, therefore, have to monitor your blood pressure regularly during the treatment. Contact your doctor immediately if you develop hypertension, chest pain or unusually severe or persistent headache (with or without sight problems).

Before administration of Dostinex, and at regular intervals during treatment, your doctor may wish to perform the following tests:
- Medical examination to assess the condition of the heart and major blood vessels (arteries and veins);
- Ultrasound of the heart, to determine whether you have a disease of the heart valves (even if you have never had any symptoms);
- Blood tests;
- An examination to assess lung function;
- A chest X-ray or other radiological examinations;
- An examination to assess kidney function;
- Tests for control of pituitary function, to exclude the presence of disease in this gland;
- Suitable tests to rule out a pregnancy. If you are treated with Dostinex and want to become pregnant, Dostinex should be discontinued one month before the planned conception (see Pregnancy and Lactation);
- Any other tests determined by the doctor.

Dostinex can increase the incidence of fibrotic reactions (scar tissue formation) in different organs which, initially, cannot be diagnosed. Consult with your doctor if the following symptoms occur **during prolonged treatment** with Dostinex (see section 4 Possible side effects):
- Difficulty breathing (dyspnoea), shortness of breath, persistent cough, chest pain, fluid in the space between the lungs and chest (pleurisy). These symptoms may indicate the beginning of fibrotic reactions in the lungs or the pleura (membrane that surrounds each lung).
- Pain in the hips/thigh, swollen ankles and/or legs (oedema), abdominal pain, formation of a mass in the abdomen. These symptoms may reveal the beginning of fibrotic reactions in different organs inside the abdomen.
- A widespread sense of weakness and fatigue, palpitations and other symptoms that may indicate the onset of fibrotic reactions affecting the heart and/or the heart valves and/or the pericardium (a thin membrane that normally surrounds the heart). If fibrotic reactions affecting the heart occur, treatment with Dostinex should be discontinued.

Tell your doctor if **during** treatment with Dostinex you or her family, or those who take care of you, notice the following symptoms (see section 4 Possible side effects):
- Drowsiness/sudden onset of sleep, which occurs even without your noticing and without warning, especially if you have ever suffered or suffer from Parkinson's disease. Your doctor may decide to reduce the dose or stop treatment (see section Driving and using machines).

- A desire/need to behave in a different way/an inability to resist the impulse, the desire or the urge to do something that may be harmful to you or others. These problems are called "impulse control disorder" and can include behaviours such as pathological gambling, eating or excessive spending, unusually urgent sexual desire, or increased thoughts or desires of a sexual nature. Your doctor may decide to adjust the dose or interrupt treatment.

If your doctor has prescribed Dostinex to treat absence of menstruation (amenorrhoea) caused by high levels of prolactin in the blood (hyperprolactinemia), your doctor may decide to perform a pregnancy test. Regular testing for pregnancy serves to reveal the possible beginning of a pregnancy because Dostinex restores fertility in women before menstruation resumes.
A pregnancy test must be performed:
- during the absence of menstruation: at least once every 4 weeks;
- after menstruation has resumed: each time menstruation is delayed longer than 3 days.

If you become pregnant during treatment with Dostinex, your doctor may decide to examine you as a precaution to check the function of the gland that produces the hormone prolactin (pituitary gland).

Other medicines and Dostinex
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

The efficacy of Dostinex may be reduced by certain medicines, including the following:
- medicines used to treat mental illness (e.g. phenothiazines, butyrophenones, thioxanthenes);
- medicines used to treat nausea and vomiting (e.g. metoclopramide).

Side effects may be increased by the use of Dostinex with other medicines, including the following:
- erythromycin and other antibiotics in the same class (macrolide antibiotics).

If your doctor has decided that you will undergo treatment with Dostinex for a long period of time, the use of Dostinex is not recommended with other drugs called ergot alkaloids.

Dostinex may cause a drop in blood pressure when moving from a sitting or lying position to a standing position. Therefore, caution is required when Dostinex is administered together with the following class of medicines:
- medicines that lower blood pressure (see section 2 Warnings and Precautions)

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking Dostinex.

<u>Pregnancy</u>
Use an effective form of contraception during treatment with Dostinex to avoid pregnancy. Dostinex can only be used during pregnancy when strictly necessary and only after careful evaluation by your doctor regarding the benefits and risks of this medicine.
If conception occurs while you are taking Dostinex, treatment should be discontinued as soon as pregnancy is confirmed.

<u>Breast-feeding</u>
Because Dostinex stops the production of milk, you should not take it if you intend to breast-feed.
If you must take Dostinex, you will have to use another method to feed your baby.

Because there is no information on whether Dostinex passes into breast milk, you should not breastfeed your baby with breast milk if Dostinex has not been effective to stop breast-feeding.

<u>Fertility</u>
If you are being treated with Dostinex and planning to become pregnant, you will have to interrupt the medication one month before the planned conception. The suspension of Dostinex one month before

conception will not decrease fertility, because the effect of the medicine lasts for about 6 months after treatment ends.

Driving and using machines
Dostinex may cause somnolence and sudden sleep episodes. If you experience these symptoms, do not drive or use any tools or machines, or engage in activities that require a high degree of attention or coordination, until they are completely resolved.

Dostinex contains lactose
Dostinex contains lactose, a type of sugar. If you have been diagnosed with an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Dostinex

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is:
- **to prevent milk production (lactation):** 2 tablets of Dostinex 0.5 mg, taken just the first day after birth.
- **to stop the production of milk after starting breastfeeding:** one half of Dostinex 0.5 mg every 12 hours for two days.
- **to reduce levels of prolactin in other conditions (hyperprolactinaemia):** you should initially take one 0.5 mg tablet in one administration or divided into two doses within a week (e.g. half a tablet on Monday and the other half tablet on Thursday). Your doctor may then decide to gradually increase the dose to find the right dose necessary to control your symptoms, and up to a maximum of 4.5 mg (9 tablets of 0.5 mg of Dostinex) per week.

You should not take more than 3 mg (6 tablets of 0.5 mg of Dostinex) per day.

When and how to take Dostinex
Take Dostinex tablets by mouth, preferably after a meal to reduce side effects. Swallow the tablets with a glass of water.

Use in children and adolescents
The use of Dostinex is not recommended in persons under 16 years of age.

Elderly patients
Experience in elderly patients is very limited. Currently, no specific risks are known.

If you take more Dostinex than you should
If you accidentally take too many tablets, you may experience symptoms such as nausea, vomiting, stomach disorders, drop in blood pressure when moving from a sitting or lying position to a standing position, confusion, psychosis (e.g. abnormal perception of reality, abnormal thinking, emotional states, behavioural abnormalities), hallucinations. If this occurs, contact your doctor immediately or go to the nearest hospital emergency room.

If you forget to take Dostinex
It is important that you do not skip the dose. If you forget to take your medicine at the usual time, take it as soon as you remember, then continue to take it as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dostinex
Your doctor will tell you how long to take Dostinex. You should not stop treatment until the doctor tells you to do so. If you stop taking Dostinex before your doctor tells you, your illness could worsen or recur.

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.

Talk to your doctor **immediately** if you experience the following symptoms because they may be severe and treatment with Dostinex must be discontinued (see Warnings and Precautions):

- **Very common side effects** (may affect more than 1 in 10 people): heart valves disorders and related disorders, e.g. inflammation of the pericardium (pericarditis) or collection of fluid in the pericardium (pericardial effusion). These disorders can manifest itself with symptoms including a widespread sense of weakness, fatigue and palpitations.
- **Other side effects** (the frequency cannot be estimated from the available data): chest pain (angina pectoris).

In patients treated with Dostinex, the following side effects were reported:

Very common side effects (may affect more than 1 in 10 people):

- headache (migraine)*;
- dizziness/vertigo*;
- nausea*;
- pain, discomfort and a sense of fullness in the stomach (dyspepsia);
- gastritis;
- abdominal pain*;
- weakness;
- fatigue.

The side effects marked with an asterisk (*) are **very common** in women being treated with Dostinex to reduce excessively high levels of prolactin (hyperprolactinemia). They are **common** in women being treated with Dostinex to prevent or stop the production of breast milk.

Weakness is **very common** in women being treated with Dostinex to reduce excessively high levels of prolactin (hyperprolactinemia). It is **uncommon** in women being treated with Dostinex to prevent or stop the production of breast milk.

Common side effects (may affect up to 1 in 10 people):

- drowsiness;
- depression;
- decrease in blood pressure (hypotension), especially in long-term treatment with Dostinex;
- lowering of blood pressure when moving from a sitting or lying position to a standing position (orthostatic hypotension);
- lowering of blood pressure without your noticing;
- hot flushes**;
- constipation;
- vomiting**;
- breast pain.

The side effects marked with two asterisks (**) are **common** in women being treated with Dostinex to reduce excessively high levels of prolactin (hyperprolactinemia). They are **uncommon** in women being treated with Dostinex to prevent or stop the production of breast milk.

Uncommon side effects (may affect up to 1 in 100 people):

- palpitations;
- breathing difficulties (dyspnoea);
- collection of fluid in the space between the lungs and the chest (pleural effusion);
- fibrotic reactions (scar tissue formation) which can also affect the lungs;

- nose bleed;
- allergies;
- temporary loss of vision in one half of the visual field, from one or both eyes (transient hemianopsia);
- sudden loss of consciousness;
- tingling or heat;
- increase in libido;
- cold fingers and toes;
- fainting;
- accumulation of fluid in different parts of the body (oedema);
- swollen ankles and/or legs;
- skin rash;
- partial balding (alopecia);
- leg cramps;
- decrease in haemoglobin values (a substance found in red blood cells). This side effect occurred in the first months after resumption of the menstrual cycle in women suffering from the absence of menstruation (amenorrhoea).

Rare side effects (may affect up to 1 in 1,000 people):
- stomach pain.

Very rare side effects (may affect up to 1 in 10,000 people):
- fibrotic reactions (scar tissue formation) of the pleura (the membrane that surrounds the lungs).

Other side effects (the frequency cannot be estimated from the available data):
- respiratory disorders;
- lung function abnormalities (respiratory failure);
- inflammation of the pleura (pleurisy);
- chest pain;
- sudden onset of sleep;
- tremors;
- vision changes;
- aggressiveness;
- delirium;
- pathological and obsessive need to have sexual intercourse or at least think about sex;
- strong impulse to engage in gambling;
- psychosis (e.g. altered perception of reality, altered thinking, altered emotional states, behavioural abnormalities);
- hallucinations;
- changes in liver function;
- raised blood levels of a substance (called creatinine phosphokinase) located mainly within the muscles;
- abnormalities in laboratory test values that assess liver function.

Pay special attention to the following side effects (see section 2 Warnings and Precautions):
Impulse control disorders, a condition that can cause harm to you or others and whose symptoms may include:
- strong impulse to gamble excessively;
- increased sex drive, pathological and obsessive need to have sexual intercourse or at least think about sex;
- impulses to make excessive purchases which are voluntary but difficult to control;
- binge eating (consumption of a higher quantity of food than normal and a higher quantity than is needed to satisfy hunger).

Tell your doctor if you experience any of these behaviours, so he or she can decide how to intervene to manage or reduce symptoms.

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. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Dostinex

Keep this medicine out of the sight and reach of children.

Do not use **Dostinex** after the expiry date, which is stated on the carton stated after EXP. The expiry date refers to the last day of that month.

Store below 30°C

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.
One 0.5 mg Dostinex tablet contains 0.5 mg cabergoline.
The other ingredients are: lactose (see section Dostinex contains lactose), leucine.

What Dostinex looks like and contents of the pack
Type I amber glass bottles with screw cap and safety closure containing silica gel
Dostinex 0.5 mg tablets are flat, oblong, white, imprinted with "PU" divided by a score line on one side and marked "700" with a slight incision above and below the central "0" on the other side.
The tablets are supplied in High-density polyethylene (HDPE) bottles with a child-resistant cap containing silica gel desiccant. This desiccant must not be removed.
Please close accurately the bottle after use. Bottle containing 2, 4 or 8 tablets.

It is possible that not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pfizer Italia S.r.l. Via Isonzo, 71 – 04100 Latina – Italy

Manufacturer
Pfizer Italia s.r.l. Località Marino Del Tronto 63100 Ascoli Piceno,Italy

This leaflet was last revised in October 2020.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers
Union of Arabic Pharmacists