Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Dostinex®
Tablets

Each tablet contains:
cabergoline 0.5 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine supresses production of prolactin and is indicated for the treatment of hyperprolactinemia and to prevent/stop breast milk production.

Therapeutic group:
Dopamine receptor agonist.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to cabergoline, 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).
- you have severe liver disease.
- you have high blood pressure in pregnancy associated with swelling and protein in the urine (toxaemia of pregnancy).
- you are being treated with anti-psychotics or have a history of mental illness associated with child-birth (puerperal psychosis).
- you are pregnant or breastfeeding.
- you will be treated with Dostinex® for a long period and have stiff and inflamed heart valves (cardiac valvulopathy).
- you have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs.

Special warnings regarding use of the medicine

Before treatment with Dostinex®, tell your doctor 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 doctor will check before starting treatment whether your heart, lungs and kidneys are in good condition. An echocardiogram (an ultrasound test of the heart) will also be 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 the treatment.

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.

Children and adolescents
There is no information regarding the safety and effectiveness of using Dostinex® in children under 16 years old.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

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).

Using this medicine and food
It is recommended you take Dostinex® with or after food to help reduce feelings of nausea or vomiting.

Using this medicine and alcohol consumption
It is recommended that you avoid alcohol as alcohol could increase the risk of dizziness.

Pregnancy, breastfeeding and fertility

Pregnancy
If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist 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 the doctor who is monitoring your pregnancy. Your doctor will monitor your pregnancy, as Dostinex® can result in congenital abnormalities if you use it during pregnancy.

Breastfeeding
As Dostinex® will stop you producing milk for your baby, you should not take this medicine if you plan to breastfeed. 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 with the medicine if this occurs.

Important information about some of this medicine's ingredients
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 medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only. The standard dosage is usually:

- **To prevent milk production (lactation):** You should take 1 mg (two 0.5 mg tablets) on the first day after delivery.
- **To stop milk secretion once you have started to breastfeed:** You should take 0.25 mg (one half of a 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 a week as a single dose or in two separate doses (e.g., half a tablet on Monday and the other half of the tablet on Thursday). Your dose will be increased gradually until you have responded fully to treatment (usually up to 2 mg a week).

Do not exceed the recommended dose.
Do not chew! The tablet may be split.

When you first start taking the medicine, 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 have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Symptoms of overdose may include nausea, vomiting, gastric complaints, low blood pressure when standing, confusion/psychosis or hallucinations.

If you forget to take the medicine at the scheduled time, take the next dose at the usual time and tell your doctor if you are having trouble remembering to take your tablets. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Dostinex®, may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of 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 or related disorders, e.g., inflammation of the pericardium (pericarditis) or leaking of fluid in the pericardium (pericardial effusion). This is a very common side effect (may affect more than 1 in 10 users). 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 side effects:

- **Very common side effects - may affect more than 1 in 10 users:** drowsiness, nausea, headache, dizziness, vertigo, stomach pain, indigestion, inflamed stomach lining, fatigue, lack of bodily strength, weakness.

- **Common side effects – may affect up to 1 in 10 users:** 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 side effects– may affect up to 1 in 100 users:** 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 side effects – may affect up to 1 in 1,000 users:** Pain in the stomach.

- **Side effects of unknown frequency (the frequency of these effects has not been established yet):** 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.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C.
- The bottle cap contains desiccant granules. Do not remove desiccant granules from cap or transfer tablets to another container. Keep the bottle tightly closed in order to protect from moisture.

- Use within 30 days of first opening.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
lactose anhydrous, leucine.

What the medicine looks like and contents of the pack:
- A flat and elongated white tablet with the letters "PU" separated by a score line engraved on one side and the number "700" engraved on the other side.
- The cardboard package contains a glass or HDPE bottle that contains 2 or 8 tablets and a desiccant.

Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer's name and address: Pfizer Italia S.r.l, Italy.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
112.13.29448

This leaflet was revised in 12/2020 according to MOH guidelines.