

# **DOSTINEX<sup>®</sup> TABLET**

Cabergoline (0.5 mg)

---

PLD Title : Dostinex Tablet  
PLD Date : 20 January 2020  
Country : Malaysia  
Reference Document : Malaysia LPD dated 02 August 2018  
Reason for Change : To align with current effective Malaysia LPD (dated 02 August 2018)  
: Revise as per new template  
: PfLEET Number: 2019-0052724, To update as per BOH comments  
: To update serial number and to remove phone number for reporting side effects

# DOSTINEX TABLET

Cabergoline (0.5 mg)

## What is in this leaflet

1. What Dostinex is used for
2. How Dostinex works
3. Before you use Dostinex
4. How to use Dostinex
5. While you are using it
6. Side effects
7. Storage and Disposal of Dostinex
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Dostinex is used for

Dostinex is used to prevent the production of milk in women after child birth, if breast-feeding is to be prevented for medical reasons.

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).

## How Dostinex works

Dostinex is an oral tablet that 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.

## Before you use Dostinex

### - When you must not use it

You are allergic to cabergoline, to other medicines called ergot alkaloids, or to any of the other ingredients in the tablet

- You have heart valve disorder
- You have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs.

## Pregnancy and lactation

If you are pregnant or planning to get pregnant, discuss this with your doctor before treatment. Before you can start using Dostinex check that you are not pregnant. You should also take precaution not to become pregnant for at least one month after you have stopped taking Dostinex.

You are advised not to breast feed as this will hinder the effect of Dostinex tablets. Since Dostinex will stop milk production, it should not be used in mothers with high prolactin levels, who wish to breast feed.

### - Before you start to use it

Tell your doctor if you have or had any of the following conditions to help him or her to decide if Dostinex is suitable for you:

- Disease that involves the heart and blood vessels (cardiovascular disease);
- Pale (white) discolouration of the fingers and toes' (Raynaud's syndrome);
- Gastric or peptic ulcer or bleeding from the stomach and intestines (gastrointestinal bleeding);
- History of serious mental or psychotic disorders;
- Reduced liver function;
- Kidney function abnormality or kidney disease;
- Pregnancy induced high blood pressure either during pregnancy or 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 behaviors such as addictive gambling, an abnormally high sex drive or an increase in sexual thoughts or feelings.

### - Taking other medicines

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

Some medicines can reduce the effectiveness of Dostinex, these include:

- Medicines used to treat mental problems (phenothiazines, butyrophenone, thioxanthenes)
- Medicines for nausea and vomiting (metoclopramide)
- Antibiotics (erythromycin)

## How to use Dostinex

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

You may be given a different dosage depending on your condition or how you react to the medicine.

### To prevent milk production (lactation):

You should take 1 mg (two 0.5 mg tablets) on the first day after delivery.

# DOSTINEX TABLET

Cabergoline (0.5 mg)

## 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 treat disorders of high prolactin levels:

You should initially take 0.5 mg per week given in one or two (one half of one 0.5 mg tablet) doses (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 of 2 mg per week or until you have responded fully to treatment.

Your doctor might prescribe a lower dose of Dostinex for you if you have severe liver disease.

Dostinex is not suitable for children under the age of 16 years.

### - When to use it

Use as directed by your doctor or pharmacist.

Dostinex should preferably be taken with food to help reduce the side effects.

### - How long to use it

Continue taking Dostinex for as long as your doctor recommends.

You should not stop until your doctor tells you. If you have any further questions on how to take this medicine, ask your doctor or pharmacist.

### - If you forget to use it

It is important not to miss your dose. If you miss 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 missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose would likely be nausea, vomiting, gastric complaints, fall in blood pressure on standing up from sitting or lying down position, confusion/psychosis or hallucinations.

### **While you are using it**

#### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Dostinex.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor if during treatment you observe few symptoms such as shortness of breath, persistent cough or chest pain, renal disorders with pain in lower limb, heart problems.

You will need to go for echocardiogram at regular interval as per doctor's advice.

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 Dostinex 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.

#### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.

- Do not give Dostinex to anyone else, even if they have the same symptoms or condition as you.
- Dostinex should not be used after the expiry date printed on the box and on the bottle label. The expiry date refers to the last day of that month.

#### - Things to be careful of

##### *Driving and using machines*

Dostinex can cause drowsiness (sommolence) and sudden onset of sleep during daily activities, in some cases without any warning signs or awareness. You must be informed of this and advised to exercise caution while driving or operating machines during treatment with Dostinex. You are advised not to drive or operate machines or engage in activities requiring mental alertness or coordination if you have already experienced sudden onset of sleep during treatment with Dostinex.

##### *Important information on some ingredients of Dostinex tablets*

Dostinex contains lactose (a type of sugar). If you have been told you have an intolerance to sugar, consult your doctor before you take Dostinex.

### **Side effects**

Like all medicines, Dostinex can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

### **Most frequent adverse reactions:**

- Dizziness
- Spinning sensation
- Headache
- Nausea
- Stomach pain
- Sleepiness
- Indigestion
- Stomach inflammation
- Lack of energy

# DOSTINEX TABLET

Cabergoline (0.5 mg)

- Tiredness
- Constipation
- Vomiting
- Breast pain
- Sudden feeling of warmth
- Depression
- Tingling or prickling sensation
- Pain in the upper abdomen
- Palpitations
- Partial vision loss
- Nose bleeding

## Other possible side effects:

- Decrease in blood pressure
- Fainting
- Leg cramps

## Side effects reported post-marketing:

- Aggression
- Loss of hair
- Increase in blood creatinine phosphokinase
- Delusions
- Shortness of breath
- Swelling
- Formation of fibrous tissues
- Liver problems
- Allergy
- Sexual addiction
- Increased sex drive
- Habitual gambling
- Liver function tests abnormality
- Mental problems
- Rash
- Breathing problems
- Disease of heart valves

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

## Storage and Disposal of Dostinex

### - Storage

Keep out of the reach and sight of children.

Store below 30°C

Dostinex tablets are supplied with desiccant in the caps. This desiccant must not be removed.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

Available as tablets each containing 0.5 mg Cabergoline.

The tablets are contained in a high-density polyethylene (HDPE) bottle and a child-resistant polypropylene (PP) cap with an inner low-density polyethylene (LDPE) desiccant canister containing silica gel.

Each bottle contains 2 or 8 tablets and is enclosed in an outer cardboard carton. Not all pack sizes may be marketed.

### - Ingredients

- Active Ingredient

Cabergoline

- Inactive ingredients

Lactose

Leucine

### - MAL number

Dostinex Tablet 0.5 mg  
MAL19971775AZ

## Manufacturer

Pfizer Italia S.r.l.  
Localita Marino del Tronto  
Ascoli Piceno  
Italy

## Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.  
Level 10 & 11,  
Wisma Averis, Tower 2,  
Avenue 5, Bangsar South,  
No. 8 Jalan Kerinchi,  
59200 Kuala Lumpur, Malaysia

## Date of revision

20/01/2020

## Serial number:

NPRA(R4/1)140120/00009

**PLD-DOSTINEX-0120**