PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DOSTINEX® 0,5 mg Tablets

Cabergoline

Contains sugar (lactose anhydrous)

Each tablet contains 75,9 mg lactose anhydrous

Read all of this leaflet carefully before you start taking DOSTINEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DOSTINEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DOSTINEX is and what it is used for
2. What you need to know before you take DOSTINEX
3. How to take DOSTINEX
4. Possible side effects
5. How to store DOSTINEX
6. Contents of the pack and other information

1. What DOSTINEX is and what it is used for

DOSTINEX is used to stop breast milk production (lactation). It can also be used if you do not want to continue to breastfeed your baby (due to medical reasons) once you have started. It is however, not recommended for routinely stopping breast milk production, for treating pain or breast enlargement after childbirth. These can be treated using painkillers.

DOSTINEX is also used to treat hyperprolactinaemic disorders; a condition which can result in high levels of prolactin (hormone that results in the stimulation of milk production) in the blood.

2. What you need to know before you take DOSTINEX

Do not take DOSTINEX:

- if you are hypersensitive (allergic) to cabergoline, other medicines called ergot alkaloids (medicines that stimulate serotonin - a chemical needed to transmit various nerve signals to the brain) or to any of the other ingredients of DOSTINEX listed in section 6
- if you are pregnant or breastfeeding
- if you have high blood pressure during pregnancy
- if you have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs
- if you have problems with your liver
- if you will be treated for DOSTINEX for a long time and have stiff and inflamed heart valves (cardiac valvulopathy)

Warnings and precautions

Take special care with DOSTINEX:

- If you suffer from disease that involves the heart and blood vessels (cardiovascular disease)
- If you have Raynaud's syndrome (extremely cold hands and feet)
- If you suffer from kidney disease
- If you have a peptic ulcer (stomach ulcer) or if you are bleeding from the stomach and intestines (symptoms may include bleeding, black or tar-like stools or being sick and bringing up blood or 'coffee-coloured granules')
- If you have a history of serious mental disease, particularly psychotic disorders
- If you suffer from postural hypotension (low blood pressure upon standing up quickly) or you are taking any medicines to lower blood pressure
- If you suffer from a build-up of fluid around the lungs, scar tissue affecting the lungs and have stiff and inflamed heart valves

- If you are treated with DOSTINEX for a long time, your doctor 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
- During treatment attention should be paid to signs of lung diseases such as breathing problems, cough and chest pain, kidney problems, lower abdominal pain and heart failure
- If you suffer from Parkinson's disease as DOSTINEX can result in episodes of feeling sleepy
- If you suffer from high blood pressure after giving birth. A lower dose of DOSTINEX is generally prescribed by your doctor to avoid potential low blood pressure

Since high levels of prolactin in the blood can be linked to pituitary tumours; it is recommended that women have their pituitary gland tested before taking DOSTINEX.

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 unusual to you and you cannot resist. These can include behaviours such as addictive gambling, abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may lower your dose or stop treatment after which normal behaviour can be expected.

Other medicines and DOSTINEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Other medicines may affect the way in which DOSTINEX works. You should therefore inform your doctor if you are taking any of the following medicines:

- other ergot alkaloids (medicines that stimulate serotonin - a chemical needed to transmit various nerve signals to the brain
- medicines that reduce the effectiveness of DOSTINEX such as phenothiazines, butyrophenones, thioxanthenes (used to treat mental illness) and metoclopramide (used to treat nausea and vomiting)
- macrolide antibiotics such as erythromycin (antibiotic – used to treat bacterial infections) as they can increase the amount of DOSTINEX in your blood and so could increase side effects

DOSTINEX with food and drink

DOSTINEX should be taken during meals.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

DOSTINEX should not be used if you are pregnant or breastfeeding your baby.

A barrier method of contraception should be used during treatment and for at least one month once you have stopped taking DOSTINEX. If you become pregnant during treatment with DOSTINEX, stop taking DOSTINEX and inform your doctor who will then monitor your pregnancy.

As DOSTINEX will stop you producing milk for your baby, you should not take this medicine if you plan to breastfeed your baby. If you need to take DOSTINEX you should use another method of feeding your baby.

Driving and using machines

DOSTINEX can cause drowsiness 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 DOSTINEX as you may put yourself or others at risk of an injury. Your doctor will decide if you can continue treatment on DOSTINEX if this occurs.

Please be cautious when you are driving or operating machinery during the first days of being treated with DOSTINEX.

It is not always possible to predict to what extent DOSTINEX may interfere with daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DOSTINEX affects them.

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. It may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take DOSTINEX

Do not share medicines prescribed for you with any other person.

Always take DOSTINEX exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

DOSTINEX tablets should be taken by mouth with meals.

Use in adults

To prevent milk production (lactation)

Take 1 mg (two 0,5 mg tablets) on the first day after delivery as a single dose.

To stop lactation once you have started to breastfeed

Take 0,25 mg (one half of DOSTINEX 0,5 mg tablet) every 12 hours for two days (1 mg total dose). A single dose greater than 0,25 mg should not be taken.

For the treatment of hyperprolactinaemic disorders (an increase in prolactin levels)

Take one 0,5 mg tablet (to be taken in one or two doses) spread out over a week. Your dose will be increased up to a maximum dose of 4,5 mg per week or until you have responded fully to treatment.

When doses higher than 1 mg per week are to be given, divide the dose throughout the week.

Your doctor will test your blood to determine the lowest dosage and will also test for prolactin levels in your blood at monthly intervals.

Use in children

DOSTINEX should not be used in children under 16 years of age.

Use in the elderly

The effect of DOSTINEX in the elderly has not been studied.

Your doctor will tell you how long your treatment with DOSTINEX will last. Do not stop treatment early. If you have the impression that the effect of DOSTINEX is too strong or too weak, tell your doctor or pharmacist.

If you take more DOSTINEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include nausea, vomiting, stomach complaints, low blood pressure when standing, confusion or hallucinations. Following accidental over dosage, your doctor will remove any unabsorbed medicine and maintain blood pressure if needed.

If you forget to take DOSTINEX

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

DOSTINEX can have side effects.

Not all side effects for DOSTINEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOSTINEX, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking DOSTINEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- heart valve related problems (valvulopathy) experienced as tiredness, weakness, short of breath
- rash
- hypersensitivity reactions (itching, watery eyes, rash, nasal congestion)
- oedema or swelling of the body

These are all very serious side effects. If you have them, you may have had a serious reaction to DOSTINEX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness
- vertigo
- headache
- stomach pain, nausea
- low blood pressure
- feeling drowsy
- depression
- hot flushes
- constipation, being sick
- breast pain

- weakness or feeling tired
- postural hypotension (low blood pressure experienced as dizziness or fainting upon standing)

Less frequent side effects:

- temporary loss of vision
- shortness of breath
- bleeding from the nose
- upper abdominal pain
- loss of consciousness due to fall in blood pressure
- loss of energy
- 'pins and needles' sensation
- cold hands and feet
- fainting
- leg cramps
- decrease in haemoglobin in women whose periods had stopped and then re-started.

Other side effects reported:

- aggression
- being deluded
- increased sexual interest and sexual drive
- strong need to gamble excessively
- psychotic disorder
- loss of hair
- an increase in the level of some enzymes in the blood
- difficulties breathing and lung failure or disease
- fibrosis (thickening of bodily tissues)
- abnormal liver and abnormal blood tests of liver function

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DOSTINEX.

5. How to store DOSTINEX

- Store all medicines out of reach of children.
- Store below 30 °C in airtight containers.
- Protect from light.
- Do not use after the expiry date stated on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOSTINEX contains

The active substance is cabergoline. Each DOSTINEX tablet contains 0,5 mg cabergoline. The other ingredients are lactose anhydrous and leucine.

What DOSTINEX looks like and contents of the pack

DOSTINEX tablets are capsule-shaped, flat, white tablets. On the one surface the letter "P" appears on a side of the score and the letter "U" on the other. On the other surface the number "700" appears with a short score in the middle of the upper and lower extremity of the tablet surface.

DOSTINEX tablets are available in amber glass bottles with an aluminium tamper evident screw cap or high-density polyethylene (HDPE) bottles with child-resistant polypropylene (PP) cap containing 2, 4 or 8 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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