

PART III: CONSUMER INFORMATION

^{PR}DOSTINEX®
Cabergoline tablets

This leaflet is part III of a three-part "Product Monograph" published when DOSTINEX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DOSTINEX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

DOSTINEX is used:

- in the treatment of hyperprolactinaemia (abnormally-high levels of prolactin in the blood);
- in the prevention of the production of breast milk in women after child birth, if it is medically advisable not to breast-feed.

What it does:

DOSTINEX works by acting on a gland called the pituitary which is located at the base of the brain. By stimulating this gland, it prevents the production of the hormone prolactin.

When it should not be used:

Do not take DOSTINEX if you:

- are allergic to cabergoline or ergot -like drugs or any of the ingredients in DOSTINEX;
- have uncontrolled high blood pressure;
- have heart valve problems (cardiac valvulopathy);
- have or have had lung or heart problems related to fibrotic tissues (tissues are hardened due to scarring.)

What the medicinal ingredient is:

Cabergoline

What the important nonmedicinal ingredients are:

leucine and lactose

What dosage forms it comes in:

DOSTINEX 0.5 mg tablets are scored, flat, white, and capsule-shaped. Each tablet contains 0.5 mg cabergoline.

WARNINGS AND PRECAUTIONS

BEFORE you use DOSTINEX talk to your doctor or pharmacist if you:

- are pregnant or plan to get pregnant;
- are breast feeding or plan to breast feed;
- have kidney problems,
- have liver problems,
- have cardiovascular problems (high or low blood pressure);

- have Raynaud's syndromes (resulting from poor blood circulation in the extremities such as fingers and toes which may turn blue and feel cold);
- have ulcer or bleeding in the stomach or intestines;
- have had pregnancy complications with high blood pressure (preeclampsia or eclampsia);
- have a history of mental illness.

If you need long term treatment with DOSTINEX, your doctor should assess your heart, lung and kidney functions before starting DOSTINEX, and continue with regular follow-up during treatment with DOSTINEX to monitor for any signs and symptoms of fibrotic disorders. Your treatment with DOSTINEX will be discontinued at the first sign of fibrotic disorders.

Impulse control disorders such as addictive gambling, excessive eating or spending and increased sex drive (libido, hypersexuality) have been reported in patients who are treated with dopamine agonists including DOSTINEX.

Aggression has been reported in patients who are treated with dopamine agonists including DOSTINEX.

DOSTINEX may cause sleepiness. Do not drive, operate machinery, or engage in any activities that requires alertness while taking DOSTINEX.

Safety and effectiveness of DOSTINEX in children have not been established.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about your other medicines, including the one you buy without prescription and natural health products. Drugs interact with DOSTINEX include:

- medicines to treat high blood pressure;
- medicines contain ergot alkaloids (e.g., to treat migraine headache);
- macrolide antibiotic (e.g., erythromycin);
- dopamine antagonists such as medicines to treat mental illness and prevent nausea (e.g., phenothiazines, butyrophenones, metoclopramide).

While taking DOSTINEX

Tell your doctor and pharmacist that you are taking DOSTINEX if you are about to start taking any new medicines.

PROPER USE OF THIS MEDICATION**Usual dose:**

Adults:

Follow your doctor's instructions carefully about how much DOSTINEX to take and when to take it.

To treat hyperprolactinaemia: initial dose is 0.5 mg per week as single dose or two divided doses. The dose may be increased monthly. Recommended dose ranges from 0.25 mg to 2 mg per week.

To prevent the production of milk, the recommended dose is two tablets taken once, on the first day after delivery of the child.

DOSTINEX should be swallowed, preferably with food.

Overdose:
Do not take more tablets than your doctor has told you to.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you should forget to take your tablet at the usual time, take it as soon as you remember up to 1 day before your next scheduled dose. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like many medicines, DOSTINEX may cause side effects.

Tell your doctor or pharmacist right away if you suffer from any of the following side effects while taking this medication:

- dizziness
- headache
- nausea or vomiting
- constipation
- abdominal pain, or heartburn, or pain in the stomach
- weakness or tiredness
- breast pain
- hot flashes
- depression
- shortness of breath
- swelling

The most common side effects are nausea, headache, dizziness/vertigo, decreases in blood pressure without any symptoms and abdominal pain. Less commonly reported side effects are palpitations, pain in the upper middle of the abdomen, somnolence, nose bleeding, and temporary blindness in one half of the visual field of one or both eyes.

Tell your doctor if you or your family/caregiver 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.

Check with your doctor or pharmacist right away if you have any problems while taking DOSTINEX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Low blood pressure		√	
Fainting		√	
Disorders related to fibrotic tissues (which may appear following these first signs and symptoms: dyspnoea, shortness of breath, lower limb oedema, persistent cough or chest pain)			√

This is not a complete list of side effects. For any unexpected effects while taking DOSTINEX, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15°C to 25°C.

You should not use your medication after the expiration date printed on the carton and label.
Keep all medications out of the reach of children. This medication could harm them.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be requested by contacting the distributor, Paladin Labs Inc., at: 1-888-867-7426 (Medical Information)

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