PART III: CONSUMER INFORMATION

APO-CABERGOLINE
Cabergoline Tablets USP

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

ABOUT THIS MEDICATION

What the medication is used for:

APO-CABERGOLINE is used:
- in the treatment of hyperprolactinemia (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:
APO-CABERGOLINE 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 APO-CABERGOLINE if you:
- are allergic to cabergoline or ergot-like drugs or any of the ingredients in APO-CABERGOLINE;
- 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:
Lactose, leucine and magnesium stearate

What dosage forms it comes in:
APO-CABERGOLINE 0.5 mg tablets are white, capsule-shaped, flat scored tablets containing 0.5 mg cabergoline.

WARNINGS AND PRECAUTIONS

BEFORE you use APO-CABERGOLINE 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 APO-CABERGOLINE, your doctor should assess your heart, lung and kidney functions before starting APO-CABERGOLINE, and continue with regular follow-up during treatment with APO-CABERGOLINE to monitor for any signs and symptoms of fibrotic disorders. Your treatment with APO-CABERGOLINE 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 cabergoline.

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

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

Safety and effectiveness of APO-CABERGOLINE 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 that interact with APO-CABERGOLINE (Cabergoline Tablets) 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 APO-CABERGOLINE
Tell your doctor and pharmacist that you are taking APO-CABERGOLINE 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 APO-CABERGOLINE (Cabergoline Tablets) to take and when to take it.

To treat hyperprolactinemia: 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.

APO-CABERGOLINE should be swallowed, preferably with food.

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

If you think you have taken too much APO-CABERGOLINE, contact your healthcare professional, 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, APO-CABERGOLINE 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 behaviors 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 APO-CABERGOLINE, 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 APO-CABERGOLINE, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature 15-25°C (59-77°F). Protect from light and moisture.

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach and sight of children. This medication could harm them.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at http://www.apotex.ca/products or by contacting the sponsor, DISpedia, Apotex's Drug Information Service, at: 1-800-667-4708.

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