

PART III: CONSUMER INFORMATION

Pr LUPRON DEPOT[®] leuprolide acetate for depot suspension

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

ABOUT THIS MEDICATION

What the medication is used for:

- LUPRON DEPOT[®] 3.75 mg (1-Month SR) and 11.25 mg (3-Month SR) are indicated in the treatment of endometriosis, including pain relief and reduction of endometriosis lesions.
- LUPRON DEPOT[®] can be taken in combination with norethindrone acetate (add-back therapy) for the initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to a period of six months.

What it does:

Endometriosis is a gynecologic disorder wherein endometrial tissue is found to be established in sites outside the endometrial cavity. LUPRON DEPOT[®] achieves a menopausal state by inhibiting the output of gonadotropins (FSH and LH) from the pituitary gland and decreasing estrogen levels.

When it should not be used:

Do not take LUPRON DEPOT[®] if you:

- are allergic to leuprolide acetate, any similar nonapeptides (e.g., histrelin, desorelin), or any of the nonmedicinal ingredients in LUPRON DEPOT[®].
- are pregnant or planning to get pregnant.

Note: You should use non-hormonal methods of contraception while receiving treatment with LUPRON DEPOT[®].

- have abnormal vaginal bleeding of unknown cause.
- are breast-feeding.

Your doctor is in the best position to decide whether or not any conditions are present that pose a risk to you. Carefully follow the instructions given by your doctor, and always contact him/her if you experience any difficulties.

What the medicinal ingredient is:

leuprolide acetate

What the important non-medicinal ingredients are:

LUPRON DEPOT[®] 3.75 mg (1-Month SR) also contains carboxymethylcellulose sodium, DL-lactic and glycolic acids copolymer, D-mannitol, gelatin, glacial acetic acid, polysorbate 80 and water for injection.

LUPRON DEPOT[®] 11.25 mg (3-Month SR) also contains carboxymethylcellulose sodium, D-mannitol, glacial acetic acid, polylactic acid, polysorbate 80 and water for injection.

What dosage forms it comes in:

LUPRON DEPOT[®] is available in a pre-filled dual-chamber syringe containing leuprolide acetate as sustained-release microspheres and must be reconstituted with a special diluent prior to intramuscular injection. LUPRON DEPOT[®] is available in two strengths: 3.75 mg (1-Month SR) and 11.25 mg (3-Month SR).

WARNINGS AND PRECAUTIONS

BEFORE you use LUPRON DEPOT[®] talk to your doctor or pharmacist if:

- You are allergic to any component of the medication
- You suspect that you are pregnant
- You are planning to become pregnant
- You take hormonal methods of contraception
- You are breast-feeding
- You have family history of osteoporosis or are a chronic user of drugs that can reduce bone mass such as anticonvulsants, corticosteroids, alcohol and/or tobacco. LUPRON DEPOT[®] can cause thinning of the bone and may pose additional risk in patients with such a history. Your doctor may prescribe norethindrone acetate (add-back therapy) to reduce the thinning effect of LUPRON DEPOT[®] on the bones.
- You have had or are suspected of having seizures, epilepsy, cerebrovascular disorder, central nervous system anomalies, or brain tumor.
- You are taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication for depression.

Signs and symptoms of endometriosis can worsen at the beginning of therapy with LUPRON DEPOT[®].

LUPRON DEPOT[®] is not recommended for use in children younger than 18 years of age or women over 65 years of age for the treatment of endometriosis.

LUPRON DEPOT[®] alone is not recommended for use beyond 6 months. Your doctor may prescribe LUPRON DEPOT[®] in combination with norethindrone acetate for an additional six months to manage the side effects produced by LUPRON DEPOT[®].

If you have been prescribed Norlutate[®], refer to the Norlutate[®] **CONSUMER INFORMATION**.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor and pharmacist if you are taking, have been taking, or are planning to take any other medicines, including non-prescription drugs (such as drug products for colds or nausea).

PROPER USE OF THIS MEDICATION

Usual Dose:

If you are taking LUPRON DEPOT[®] 3.75 mg (1-Month SR), report to your doctor **once every month** for your injection.

If you are taking LUPRON DEPOT[®] 11.25 mg (3-Month SR), report to your doctor **once every three months** for your injection.

It is very important that your doctor check your progress at regular medical visits. Your doctor, or healthcare provider, will administer LUPRON DEPOT[®] for you during your scheduled visits.

If you need more information, ask your doctor.

Overdose:

In case of 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 miss an appointment by a few days, it should not disrupt the benefits of treatment, but keeping a consistent schedule of LUPRON DEPOT[®] injections is an important part of treatment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Postmarketing reports of convulsions have been observed in patients taking LUPRON DEPOT[®]. These included patients in the female and pediatric populations, patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs. Convulsions have also been reported in patients in the absence of any of the conditions mentioned above.

After taking LUPRON DEPOT[®], your estrogen levels will initially increase and then decrease over several weeks.

The following side effects are commonly experienced after the first few weeks and occur due to decreased levels of estrogen in the body:

- hot flashes / sweats
- gastrointestinal disturbances
- decreased libido
- muscle or joint pain
- breast tenderness / pain and/or vaginitis (inflammation of the vagina)
- emotional changes such as feeling depressed
- headache / migraine
- nervousness / rapid heart beat

Should these side effects persist or if they are severe, contact your doctor immediately.

A local skin reaction may occur: itching, redness, burning and/or swelling at the injection site. These reactions usually are mild and disappear after a few days. If they persist or worsen, tell your doctor.

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	
Common	Headache	✓		
	Hot flashes / sweats		✓	
	Skin reactions including reaction at site of injection		✓	
	Vomiting / nausea	✓		
Uncommon	Abnormal swelling or numbness of limbs		✓	
	Convulsion		✓	
	Severe bone pain		✓	
	Severe pain in chest or abdomen		✓	
	Vision changes		✓	
Reported from post-marketing with unknown frequency	New onset or worsening of shortness of breath, especially with exertion; dry cough/interstitial lung disease, an inflammation of lung tissue		✓	

This is not a complete list of side effects. For any unexpected effects while taking LUPRON DEPOT[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15 and 25°C. Protect from freezing.

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 on line 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
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at <http://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 found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

This leaflet was prepared by Abbott Laboratories, Limited.

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