

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:**

Both LUPRON DEPOT[®] (leuprolide acetate for depot suspension) 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, for 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:

LUPRON DEPOT[®] should not be used if:

- You are allergic to leuprolide acetate, any similar nonapeptides (e.g., histrelin, desorelin), or any of the nonmedicinal ingredients in LUPRON DEPOT[®].
- You are pregnant or planning to get pregnant.
Note: You should use non-hormonal methods of contraception while receiving treatment with LUPRON DEPOT[®].
- You have abnormal vaginal bleeding of unknown cause.
- You 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 nonmedicinal ingredients are:**1-Month SR**

Non-medicinal ingredients include: purified gelatin, DL-lactic and glycolic acids copolymer, and D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, and glacial acetic acid.

3-Month SR

Non-medicinal ingredients include: polylactic acid, D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, and glacial acetic acid.

What dosage forms it comes in:

LUPRON DEPOT[®] 3.75 mg (1-Month SR) is available in a prefilled dual-chamber syringe that contains 3.75 mg of leuprolide acetate as sustained-release microspheres and must be reconstituted with a special diluent prior to intramuscular administration once a month.

LUPRON DEPOT[®] 11.25 mg (3-Month SR) is available in a prefilled dual-chamber syringe that contains 11.25 mg of leuprolide acetate as sustained-release microspheres and must be reconstituted with a special diluent prior to intramuscular administration once every three months.

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.

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[®] is not recommended for use beyond 6 months.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor and pharmacist if you are taking, have been taking, or 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 visit.

If you need more information, ask your doctor.

HOW TO STORE IT

Store between 15 and 25°C (59 -77°F). Protect from freezing.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

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	
Uncommon	Abnormal swelling or numbness of limbs		✓	
	Severe bone pain		✓	
	Severe pain in chest or abdomen		✓	
	Vision Changes		✓	
Common	Headache	✓		
	Hot flashes / sweats		✓	
	Skin reactions including reaction at site of injection		✓	
	Vomiting / nausea	✓		

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

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 at: 1-800-361-7852.

This leaflet was prepared by Abbott Laboratories, Limited.

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