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:

Endometriosis:

Use LUPRON DEPOT 3.75 mg (1-Month slow release) and 11.25 mg (3-Month slow release) for up to 6 months:

- **as a sole treatment for:** endometriosis, including pain relief and reducing lesions
- **as a sole treatment for women close to menopause who do not want surgery:** may relieve symptoms
- **as a sole treatment for women close to menopause along with surgery:** may relieve symptoms
- **as a combination treatment with 5 mg norethindrone acetate:** for initial treatment or when symptoms return

Uterine Fibroids (before surgery)

Use LUPRON DEPOT 3.75 mg (1-Month slow release) for up to 3 months:

- **as a combination treatment with an iron supplement:** to improve anemia before surgery for uterine fibroids

What it does:

LUPRON DEPOT works to inhibit the production of gonadotropins from the pituitary gland, thereby decreasing estrogens to postmenopausal levels in premenopausal women.

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 other ingredients in LUPRON DEPOT
- are pregnant or planning to get pregnant
- have abnormal vaginal bleeding of unknown cause
- are breast-feeding

You must use non-hormonal methods of birth control while receiving LUPRON DEPOT.

What the medicinal ingredient is:

leuprolide acetate

What the non-medicinal ingredients are:

LUPRON DEPOT 3.75 mg (1-Month slow release) 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 slow release) also contains carboxymethylcellulose sodium, D-mannitol, glacial acetic acid, polylactic acid, polysorbate 80 and water for injection.

What dosage forms it comes in:

Pre-filled syringes with two parts. The two parts must be mixed prior to giving the intramuscular injection.

- First part has leuprolide acetate.
- Second part has a special diluent.

LUPRON DEPOT comes in two strengths:

- 3.75 mg (1-Month slow release)
- 11.25 mg (3-Month slow release)

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.
- 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.

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

LUPRON DEPOT is to be given to you:

- as an injection into the muscle (intramuscular injection).
- under the supervision of a health professional.

Usual Dose:

Endometriosis:

- 3.75 mg (1-Month slow release) once a month for 6 months, OR
- 11.25 mg (3-Month slow release) once every 3 months for 6 months.

Uterine Fibroids (before surgery):

- 3.75 mg (1-Month slow release) once a month for up to 3 months.

For the 3 months you are on LUPRON DEPOT: take an oral iron supplement every day.
Your doctor or pharmacist will tell you how much iron to take every day.

Overdose:

In case of overdose, contact a healthcare 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

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

Possible common side effects with the use of LUPRON DEPOT include:

- hot flashes, excessive sweats
- gastrointestinal problems, nausea, vomiting
- decreased libido
- muscle or joint pain
- weakness
- breast tenderness/pain and/or vaginitis (infection or inflammation of the vagina)
- emotional changes such as feeling depressed
- headache/migraine
- upset sleep
- nervousness/rapid heart beat
- edema (swelling, water retention)
- weight gain or loss
- skin reaction at the injection site such as itching, redness, burning, and/or swelling
- acne
- menstrual cramps (dysmenorrhea)

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

Side effects reported after the drug was available for sale (postmarketing) include:

- convulsion
- liver problems, including serious liver injury
- serious allergic reaction (anaphylaxis and anaphylactoid)
- inflammation of the lung (interstitial lung disease)
- pituitary apoplexy; symptoms include sudden headache, vomiting, visual changes, problem with eye muscle movement (ophthalmoplegia), altered mental status, and sometimes cardiovascular collapse

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 or dry cough, often seen with exertion, as potential symptoms of pulmonary fibrosis or interstitial lung disease (inflammation of the lung)		✓	

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 SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- **Visiting the Web page on Adverse Reaction Reporting (**https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html**) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

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

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at 1-888-704-8271.

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