

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION FOR GYNECOLOGY

PrLUPRON DEPOT®

leuprolide acetate for depot suspension

Read this carefully before you start taking **LUPRON DEPOT** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LUPRON DEPOT**.

What is LUPRON DEPOT used for?

Endometriosis:

LUPRON DEPOT 3.75 mg (1-Month slow release) and 11.25 mg (3-Month slow release) is for the **sole treatment** of:

- endometriosis, including pain relief and reducing lesions
- **women close to menopause who do not want surgery:** may relieve symptoms
- **women close to menopause along with surgery:** may relieve symptoms

LUPRON DEPOT 3.75 mg (1-Month slow release) and 11.25 mg (3-Month slow release) is for the **combination treatment with 5 mg norethindrone acetate** for initial treatment or when symptoms return.

Uterine Fibroids (before surgery)

LUPRON DEPOT 3.75 mg (1-Month slow release) is for the **combination treatment with an iron supplement** to improve anemia before surgery for uterine fibroids.

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 and uterine fibroids.

How does LUPRON DEPOT work?

LUPRON DEPOT stops the production of a hormone called gonadotropins from a gland. This decreases estrogen to postmenopausal levels in premenopausal women.

What are the ingredients in LUPRON DEPOT?

Medicinal ingredients: leuprolide acetate

Non-medicinal ingredients: carboxymethylcellulose sodium, D-mannitol, DL-lactic and glycolic acids copolymer (only for LUPRON DEPOT 3.75 mg), glacial acetic acid, polylactic acid (only for LUPRON DEPOT 11.25 mg), polysorbate 80, gelatin, and water for injection.

LUPRON DEPOT comes in the following dosage forms:

Powder for suspension: 3.75 mg and 11.25 mg

LUPRON DEPOT comes in a pre-filled syringe.

LUPRON DEPOT also comes with a special diluent. The powder must be mixed with the diluent before intramuscular injection.

Do not use LUPRON DEPOT if you:

- are allergic to leuprolide acetate, any similar medications (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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LUPRON DEPOT. Talk about any health conditions or problems you may have, including if:

- 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 a bone disease (osteoporosis) or are a chronic user of drugs that can reduce bone mass. These can include drugs to treat seizures, corticosteroids, alcohol and/or tobacco. This is because LUPRON DEPOT can cause thinning of the bone.
- You have had or are suspected of having seizures, epilepsy, problems with blood flow to your brain (cerebrovascular disorder), problems with your central nervous system, or a brain tumor.
- You are taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication. These are used to treat depression.
- You may experience an increase in your cholesterol levels during treatment with LUPRON DEPOT.

Tell your healthcare professional about all the medicines you take or are planning to take, including any drugs, non-prescription drugs (such as drug products for colds or nausea), vitamins, minerals, natural supplements or alternative medicines.

How to take LUPRON DEPOT:

Your doctor or a nurse will administer LUPRON DEPOT for you during your scheduled visits.

LUPRON DEPOT will be injected into your muscle.

Regular injections are important!

It is very important that your doctor check your progress at regular medical visits.

Usual dose:

Endometriosis:

If you are taking LUPRON DEPOT 3.7 mg (1-Month slow release), go to your doctor or nurse for your injection once every month for 6 months.

If you are taking LUPRON DEPOT 11.25 mg (3-Month slow release), go to your doctor or nurse for your injection once every three 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:

If you think you have taken too much Lupron Depot, contact your healthcare professional, 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 you must follow your drug administration schedules for the therapy to be successful.

What are possible side effects from using LUPRON DEPOT?

These are not all the possible side effects you may feel when taking LUPRON DEPOT. If you experience any side effects not listed here, contact your healthcare professional.

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 heartbeat
- 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:

- hypotension (low blood pressure)
- convulsion, peripheral neuropathy (weakness, numbness of the limbs, nerve damage) and spinal fracture/paralysis
- white blood cell count decreased
- liver problems, including serious liver injury
- serious allergic reaction (anaphylaxis and anaphylactoid)
- inflammation of the lung (interstitial lung disease), pulmonary fibrosis (lung disease), dyspnea (difficulty breathing)
- menstrual disorders
- pituitary apoplexy; symptoms include sudden headache, vomiting, visual changes, problem with eye muscle movement (ophthalmoplegia), rash, urticaria (raised red, itchy areas on the skin called hives), tenosynovitis-like symptoms (inflammation of the tendon), altered mental status, and sometimes cardiovascular collapse

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	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		✓	
UNKNOWN FREQUENCY (reported from postmarketing)			
Pulmonary fibrosis or interstitial lung disease (inflammation of the lung) : new onset or worsening of shortness of breath or dry cough, often seen with exertion		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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

Storage:

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

If you want more information about LUPRON DEPOT:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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