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 is used in the palliative treatment of prostate cancer. Palliative treatment is the relief of symptoms associated with a disease; it is not a cure.

What it does:

Leuprolide acetate is chemically similar to gonadotropin-releasing hormone (GnRH or LHRH); a hormone which occurs naturally in your body. Normally, your body releases small amounts of LHRH and this leads to events which stimulate the production of sex hormones. However when you inject LUPRON DEPOT, the normal events that lead to sex hormone production are interrupted and testosterone is no longer produced by the testes. Decreasing the levels of testosterone leads to decreased symptoms associated with prostate cancer.

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 non-medicinal ingredients in LUPRON DEPOT
- in women who are or may become pregnant
- in women who are breast-feeding

What the medicinal ingredient is:

leuprolide acetate

What the non-medicinal ingredients are:

LUPRON DEPOT 7.5 mg (1-Month slow release) also contains: carboxymethylcellulose sodium, DL-lactic and glycolic acids copolymer, D-mannitol, glacial acetic acid, polysorbte 80, gelatin, and water for injection.

LUPRON DEPOT 22.5 mg (3-Month slow release) and 30.0 mg (4-month slow release) also contain: 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 three strengths: 7.5 mg (1-Month slow release), 22.5 mg (3-Month slow release) and 30.0 mg (4-Month slow release).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

LUPRON DEPOT should be prescribed by a doctor experienced with this type of drug.

LUPRON DEPOT may cause:
- worsening of symptoms of prostate cancer at the beginning of the treatment
- bone thinning (osteoporosis)

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

- You are allergic to any component of the medication.
- You have previous history of obstructive uropathy (difficulty urinating due to a block in the urinary tract).
- 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.
- 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 selective serotonin reuptake inhibitor (SSRI) medication for depression.
- You have a history of heart disease or disorders, or have a genetic heart condition called “long QT syndrome”.
- You have high blood sugar (diabetes). LUPRON DEPOT may affect your blood sugar and you may need to test your blood sugar more frequently while receiving treatment with LUPRON DEPOT.
- You have low red blood cell counts. LUPRON DEPOT may cause a decrease in red blood cells (anemia).

During the first few weeks of treatment with LUPRON DEPOT, you may experience worsening of symptoms or onset of new symptoms, including bone pain, presence of blood in the urine or difficulty urinating.

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).

In particular, if you take the following medicines:

- medicines used to correct heart rhythm such as quinidine, disopyramide, amiodarone, dronedarone, sotalol, dofetilide, ibutilide (e.g., Corvert®), flecainide (e.g., Tambocor®), propafenone (e.g., Rythmol®)
- medicines used to treat schizophrenia such as chlorpromazine
- medicines to treat depression such as amitriptyline, nortriptyline
- morphine-like medicines (e.g., methadone)
- certain antibiotics and antimicrobials such as erythromycin, clarithromycin (e.g., Biaxin®), azithromycin (e.g., Zithromax®), moxifloxacin (e.g., Avelox®)
- antimalarials (e.g., quinine)
- antifungals
- medicines used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery such as ondansetron (e.g., Zofran®)
- medicines used for the relief of bronchospasm in conditions like asthma and chronic obstructive pulmonary disease such as salbutamol (e.g., Ventolin®)

PROPER USE OF THIS MEDICATION

Usual dose:

If you are taking LUPRON DEPOT 7.5 mg (1-Month slow release) report to your doctor **once every month** for your injection.

If you are taking LUPRON DEPOT 22.5 mg (3-Month slow release), report to your doctor **once every three months** for your injection.

If you are taking LUPRON DEPOT 30.0 mg (4-Month slow release), report to your doctor **once every four 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 healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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.

In the first few weeks of taking LUPRON DEPOT, your testosterone levels will initially increase and then decline over several weeks. During this period some patients may experience worsening of urinary symptoms and/or a temporary increase in bone pain. **Should this occur, contact your doctor immediately.**

The following side effects are commonly experienced after the initial rise and occur due to decreasing levels of testosterone in the body:

- general pain or flu-like symptoms
- hot flashes/sweats
- joint and muscle pain
- emotional changes such as feeling depressed
- worsening urinary symptoms

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

Notify your doctor if you develop new or worsened symptoms of depression after beginning LUPRON DEPOT treatment.

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	Decrease in testicular size		√	
	Headache	√		
	Hot flashes		√	
	Impotence/ decrease in libido		√	
	Itching rash		√	
	Skin reactions including reaction at site of injection		√	
Uncommon	Abnormal swelling or numbness of limbs		√	
	Convulsion		√	
	Severe bone pain		√	
	Severe pain in chest or abdomen		√	
	Vision changes		√	
Reported from postmarket-ing with unknown frequency	New onset or worsening of shortness of breath, especially with exertion; dry cough/interstitial lung disease, an inflammation of lung tissue		√	
	Serious liver injury (yellow skin, yellow eyes, nausea/vomiting, decreased or loss of appetite, fatigue, itching, abdominal pain and bleeding and bruising)		√	√

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 health 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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