PART III: CONSUMER INFORMATION

[Pr]LUPRON®
leuprolide acetate injection

This leaflet is PART III of a three-part Product Monograph published when LUPRON® 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®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- LUPRON® 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®, 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® 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®
- 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:

Each 2.8 mL multiple-dose vial contains **benzyl alcohol**, sodium chloride, and sterile water for injection. Each vial also contains sodium hydroxide and/or acetic acid.

What dosage forms it comes in:

LUPRON® is a drug which contains 5 mg of leuprolide acetate per mL. It comes in 2.8 mL multiple-dose vials. LUPRON® is supplied as a 14-day kit.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

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

BEFORE you use LUPRON® 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® 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® may affect your blood sugar and you may need to test your blood sugar more frequently while receiving treatment with LUPRON®.
- You have low red blood cell counts. LUPRON® may cause a decrease in red blood cells (anemia).

During the first few weeks of treatment with LUPRON®, 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 nonprescription 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:

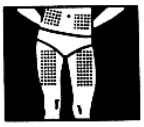
The recommended dose of LUPRON® is 1 mg (0.2 mL), as a single daily subcutaneous injection.

Only a small amount of LUPRON® is needed once a day. Use the recommended ½ cc presterilized disposable syringe (see Instructions for Use Leaflet). Syringes are provided in the Patient Administration Kit.

Change the site of injection as instructed by your doctor.

As a guide, the usual sites of injection are indicated below:

SUGGESTED ROTATION OF THE INJECTION SITE



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:

Follow these instructions unless instructed otherwise by your doctor: if you miss an injection at the usual time, take it as soon as you remember, if you remember on the same day. If not, do not take the missed dose at all. Simply wait until it is time for your next dose. Do not take two doses at once.

Do not stop your daily injections because you feel better. You need one injection a day to make sure LUPRON® keeps working for you.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Postmarketing reports of convulsions have been observed in patients taking LUPRON®. 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®, 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® 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		√	
	Difficulty urinating		√	
	Headache	√		
	Hot flashes		√	
	Impotence/ decrease in libido		√	
	Itching rash		√	
	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 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®, contact your doctor or pharmacist.

HOW TO STORE IT

Store LUPRON® vials or kits in the refrigerator (2 to 8°C) and protect from light (keep in carton until use).

As with other medications, KEEP OUT OF REACH OF CHILDREN.

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 0701D
    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

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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