

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

P^rLUPRON[®]

leuprolide acetate injection

Read this carefully before you start taking **LUPRON** 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**.

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)

What is LUPRON 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.

How does LUPRON work?

Leuprolide acetate is similar to gonadotropin-releasing hormone (GnRH or LHRH). This is a hormone that is naturally made in your body. Normally, your body releases small amounts of LHRH and this leads to the production of sex hormones. However, when you inject LUPRON, sex hormone production is stopped and testosterone is no longer produced by the testes. When the level of testosterone is decreased in your body, your symptoms will get better.

What are the ingredients in LUPRON?

Medicinal ingredients: leuprolide acetate

Non-medicinal ingredients: benzyl alcohol, sterile water for injection, sodium chloride, sodium hydroxide and/or acetic acid.

LUPRON comes in the following dosage forms:

Solution: 5 mg / mL

LUPRON comes in 2.8 mL vials.

LUPRON is supplied as a 14-day kit. Each kit contains:

- One multidose vial of LUPRON
- 14 syringes
- Two Patient Medication Information leaflets. One is for Central Precocious Puberty, the other is for Prostate Cancer.
- One Instructions for Use leaflet

Do not use LUPRON if:

- you are allergic to leuprolide acetate, any similar medications (e.g., histrelin, desorelin), or any of the non-medicinal ingredients in LUPRON

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

- you have had or have difficulty urinating due to a block in the urinary tract (obstructive uropathy) and/or a spinal cord tumor (metastatic vertebral lesions).
- 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 can cause thinning of the bone and may pose additional risk in these patients.
- you have had or are suspected of having seizures, epilepsy, problems with blood flow to the 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 selective serotonin reuptake inhibitor (SSRI) medication. These are used to treat 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).
- you have problems with your liver

- you have depression or other mental disorders

During the first few weeks of treatment with LUPRON, your symptoms may get worse or you may develop new symptoms. These can include bone pain, neuropathy (tingling, numbness or pain in the affected area), presence of blood in the urine or difficulty urinating.

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.

The following may interact with LUPRON:

- 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[®])

How to take LUPRON:

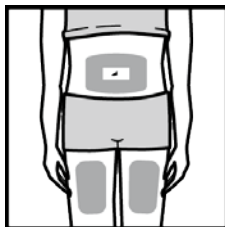
Only a small amount of LUPRON is needed once a day.

Only use the provided ½ cc disposable syringe (see **Instructions for Use** leaflet). Syringes are provided in the Patient Administration Kit. Each syringe should only be used only once.

Change the site of injection as instructed by your doctor.

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

ACCEPTABLE INJECTION SITES



Before each use, check that the solution is clear and colorless (has no color) and does not have solid particles.

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 the doctor check your progress at regular medical visits.

Usual dose:

Take one injection a day, as prescribed by your doctor.

The recommended dose of LUPRON is 1 mg (0.2 mL).

Overdose:

If you think you have taken too much Lupron, 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 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. Wait until it is time for your next dose. Do not take two doses at once.

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

What are possible side effects from using LUPRON?

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

Postmarketing reports of convulsions have been observed in patients taking LUPRON. These included female patients and children, patients with a history of seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorders), problems with the central nervous system or tumors. Postmarketing reports of cardiac arrest (heart stops beating), low blood pressure (hypotension), heart attack (myocardial infarction), sudden cardiac death, spinal fracture/paralysis, decreased white blood cell count, serious liver injury, problem with sunlight

(photosensitivity reactions), inflammation of the tendon (tenosynovitis-like symptoms), prostate pain, a solid swelling of clotted blood within the tissues (hematoma), induration, inflammation, interstitial lung disease, and pulmonary fibrosis have been observed. Postmarketing reports have also been observed, 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
- 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: redness, burning, and/or swelling, pain 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 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			
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		✓	
UNKNOWN FREQUENCY (reported from postmarketing)			
Interstitial lung disease or pulmonary fibrosis (inflammation of the lung): 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		✓	✓

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 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.

If you want more information about LUPRON:

- 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.

This leaflet was prepared by AbbVie Corporation.

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