

PART III: CONSUMER INFORMATION

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[®] (leuprolide acetate) Injection 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 LH-RH) a hormone which occurs naturally in your body. Normally, your body releases small amounts of LH-RH 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 DEPOT[®] should not be used:

- If you are allergic to leuprolide acetate, any similar nonapeptides (e.g., histrelin, desorelin), or any
- In women who are or may become pregnant.
- In women who are breast-feeding.

What the medicinal ingredient is:

Leuprolide acetate

What the important nonmedicinal ingredients are:

1-Month SR

Non-medicinal ingredients include: purified gelatin, DL-lactic and glycolic acids copolymer, and D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, and glacial acetic acid.

3-Month SR and 4-Month SR

Non-medicinal ingredients include: polylactic acid, D-mannitol, carboxymethylcellulose sodium, polysorbate 80, water for injection, and glacial acetic acid.

What dosage forms it comes in:

LUPRON DEPOT[®] 7.5 mg (1-Month SR) is available in a prefilled dual-chamber syringe that contains 7.5 mg of leuprolide acetate as sustained-release microspheres and must be reconstituted with a special diluent prior to intramuscular administration once a month.

LUPRON DEPOT[®] 22.5 mg (3-Month SR) is available in a prefilled dual-chamber syringe that contains 22.5 mg leuprolide acetate as sustained-release microspheres and must be reconstituted with the appropriate diluent prior to intramuscular injection once every three months.

LUPRON DEPOT[®] 30.0 mg (4-Month SR) is available in a prefilled dual-chamber syringe that contains 30 mg leuprolide acetate as sustained-release microspheres and must be reconstituted with the appropriate diluent prior to intramuscular injection once every four months.

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 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.

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 planning to take any other medicines, including non-prescription drugs (such as drug products for colds or nausea).

PROPER USE OF THIS MEDICATION

Usual dose:

If you are taking LUPRON DEPOT[®] 7.5 mg (1-Month SR) report to your doctor **once every month** for your injection. If you are taking LUPRON DEPOT[®] 22.5 mg (3-Month SR), report to your doctor **once every three months** for your injection. If you are taking LUPRON DEPOT[®] 30.0 mg (4-Month SR), 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 visit.

If you need more information, ask your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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.

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 | |
| Uncommon | Abnormal swelling or numbness of limbs | | ✓ | |
| | Severe bone pain | | ✓ | |
| | Severe pain in chest or abdomen | | ✓ | |
| | Vision Changes | | ✓ | |
| Common | Decrease in testicular size | | ✓ | |
| | Headache | ✓ | | |
| | Hot flashes | | ✓ | |
| | Impotence/ decrease in libido | | ✓ | |
| | Itching Rash | | ✓ | |
| | Skin reactions including reaction at site of injection | | ✓ | |

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 (59 -77°F). Protect from freezing.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
 toll-free fax 866-678-6789
 By email: cadmp@hc-sc.gc.ca

By regular mail:
 National AR Centre
 Marketed Health Products Safety and Effectiveness Information Division
 Marketed Health Products Directorate
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.abbott.ca> or by contacting the sponsor, Abbott Laboratories, Limited at: 1-800-361-7852.

This leaflet was prepared by Abbott Laboratories, Limited.

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