

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® (leuprolide acetate for depot suspension) is indicated in the treatment of children with central precocious puberty.

What is precocious puberty:

Precocious puberty occurs when girls under the age of 8 or boys under the age of 9 begin to develop signs of sexual maturity.

Signs and symptoms:

- Girls develop breasts and may have monthly periods.
- The penis and testicles of boys grow larger.
- Behavior may change; children may become aggressive or moody.
- Pubic hair grows in both sexes.
- Children may have oily skin and/or acne.
- Children may be the tallest in the class; there is a sudden growth spurt like that usually seen in teenagers.

Why does it happen:

In most cases, there is no special reason for this early development. It is not caused by anything we do and is not necessarily passed on from parents to children. However, there may be some physical problem, like a tumor, causing precocious puberty; this would require other treatment. A doctor will need to perform tests to rule out some possible physical causes.

What the medication does:

LUPRON DEPOT® is a hormone-like agent. It is given by injection **once a month** to adjust your child's body clock (daily injections are also available).

- Your child will stop making some hormones at adult levels.
- Pubertal changes (pubic hair, girl's period, breasts, etc.) should stop and may even become less obvious.
- Growth rate becomes more normal.
- When it's right for your child, your child's doctor will stop administering the shots and puberty will begin again.

When it should not be used:

LUPRON DEPOT® should not be used:

- If your child is allergic to leuprolide acetate, any similar nonapeptides (e.g., histrelin, desorelin), or any of the

nonmedicinal ingredients in LUPRON DEPOT®

- In women who are or pregnant or breast-feeding.

What the medicinal ingredient is:

Leuprolide acetate

What the important nonmedicinal ingredients are:

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.

What dosage forms it comes in:

LUPRON DEPOT® 3.75, 7.5, 11.25 and 15.0 mg (1-Month SR) is supplied in single-dose kits containing one prefilled dual-chamber syringe with 23 G needle, two alcohol swabs, Patient Information Leaflet, Special Instructions for Use, and Package Insert.

WARNINGS AND PRECAUTIONS**Before your child takes LUPRON DEPOT®, tell your child's doctor if:**

Your child has a family history of osteoporosis or is 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.

INTERACTIONS WITH THIS MEDICATION

Tell your child's doctor and pharmacist if your child is taking, has 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:**

Your child only needs **one injection a month**, as prescribed by your child's doctor. It is very important that the doctor check your child's progress at regular medical visits. Your child's doctor, or healthcare provider, will administer LUPRON DEPOT® during your child's scheduled visit.

Missed Dose:**Regular injections are important!**

Adherence to 4-week drug administration schedules must be accepted if therapy is to be successful. For best results, your child should have the right amount of LUPRON DEPOT® in his or her body at all times. If your child misses a dose, the pubertal development could restart.

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 child's hormone levels will initially increase and then decline over several weeks. During this period some patients may experience worsening of symptoms.

The following items are not necessarily problems, but your child's doctor will want to know about them. Call your child's doctor or tell the doctor at your child's next appointment if:

- Pubertal changes continue.
- Your daughter has a period, especially after the first month of treatment with LUPRON DEPOT[®].
- Your child has substantial mood swings (write down the date this happens).
- You observe any behavioral changes in your child (boys may become aggressive; girls may become moody).

A 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	Headache	✓		
	Itching Rash		✓	
	Skin reactions including reaction at site of injection		✓	
	Vomiting / nausea	✓		

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: cadrmpp@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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