

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION FOR CENTRAL PRECOCIOUS PUBERTY

PrLUPRON DEPOT®

leuprolide acetate for depot suspension

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

What is LUPRON DEPOT used for?

- LUPRON DEPOT (leuprolide acetate injection) is for the treatment of children with central precocious puberty.

How does LUPRON DEPOT work?

LUPRON DEPOT is a hormone-like agent. It is given by injection **once a month** to adjust your child's body clock.

- 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 giving the shots and puberty will begin again.

What are the ingredients in LUPRON DEPOT?

Medicinal ingredients: leuprolide acetate

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

LUPRON DEPOT comes in the following dosage forms:

Powder for suspension: 3.75 mg and 7.5 mg.

LUPRON DEPOT comes in a pre-filled syringe.

LUPRON DEPOT also comes with a special diluent. The powder must be mixed with the diluent before intramuscular injection.

Do not use LUPRON DEPOT:

- if your child is allergic to leuprolide acetate, any similar medications (e.g., histrelin, desorelin), or any of the non-medicinal ingredients in LUPRON DEPOT
- in patients who are pregnant or may become pregnant

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

- has a family history of a bone disease (osteoporosis) or is 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 DEPOT can cause thinning of the bone and may pose additional risk in these patients. Once the treatment has ended, this bone loss may stop. Bone mass may return to normal levels in late adolescence.
- has had or is suspected of having seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorder), problems with their central nervous system, or a brain tumor.
- is taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication for depression.
- has had or is suspected of having mental (psychiatric) events. These can include crying, irritability, impatience, anger and/or depression

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.**How to take LUPRON DEPOT:**

Your child only needs one injection a month.

Your child's doctor or nurse will administer the injection during your child's scheduled visits.

LUPRON DEPOT will be injected into your child's muscle.

Regular injections are important!

It is very important that the doctor check your child's progress at regular medical visits.

Usual dose:

The recommended starting dose of LUPRON DEPOT is:

- 7.5 mg for children weighing less than 25 kg
- 11.25 mg for children weighing between 25 kg and 37.5 kg
- 15 mg for children weighing more than 37.5 kg

The maximum dose is 15 mg per month.

Overdose:

If you think you have taken too much Lupron Depot, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

Your child must follow the 4-week drug administration schedules for the therapy 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 child's doctor.

What are possible side effects from using LUPRON DEPOT?

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

Postmarketing reports of convulsions have been observed in patients taking LUPRON DEPOT. These included adult 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 decreased white blood cell count, disorder of the nerves which can cause weakness and tingling (neuropathy), increased sweating (hyperhidrosis), problems with sunlight (photosensitive reaction), raised red, itchy areas on the skin called hives (urticaria), weight increased, inflammation of the tendon (tenosynovitis-like symptoms) have been observed. Postmarketing reports have also been observed 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 child's hormone levels will initially increase and then decline over several weeks. Your child's symptoms may get worse.

Your child may have new or worsened mental (psychiatric) problems. Mental problems may include emotional symptoms such as:

- crying
- irritability
- restlessness (impatience)
- anger
- acting aggressive

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 behavioural changes in your child (boys may become aggressive; girls may become moody).

A skin reaction may occur: 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 child's 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			
Headache	✓		
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		✓	

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 between 15 and 25°C. Protect from freezing.

If you want more information about LUPRON DEPOT:

- 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.

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