

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

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**.

What is LUPRON used for?

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

How does LUPRON work?

LUPRON is a hormone-like agent. It is given by injection once a day 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 is right for your child, your child's doctor will stop giving your child the shots. Puberty will begin again.

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:

- your child is allergic to leuprolide acetate, any similar medications (e.g., histrelin, desorelin), or any of the non-medicinal ingredients in LUPRON
- 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. 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 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.
- has had or is suspected of having mental (psychiatric) events. These can include crying, irritability, impatience, anger and/or depression.
- is taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any Selective Serotonin Reuptake Inhibitors (SSRI) medication. These are used to treat depression.

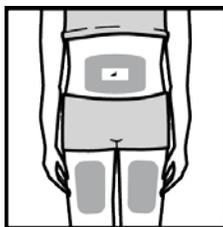
Tell your healthcare professional about all the medicines you take or are planning to take, including any drugs, non-prescription drugs (such as drug products for colds or nausea), vitamins, minerals, natural supplements or alternative medicines.

How to take LUPRON:

- Only a small amount of LUPRON is needed.
- Give your children the injection 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 child's 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 child's daily injections because they feel better. Your child needs one injection a day to make sure LUPRON keeps working for him/her.

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

Usual dose:

- Give your child one injection a day, as prescribed by your child's doctor.
- The recommended starting dose of LUPRON is 50 mcg/kg/day.
- Your doctor will tell you how much LUPRON to give your child.
- The recommended dose will vary by your child's weight.
- Your doctor may increase the dose to a maximum of 100 mcg/kg/day.

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 your child misses an injection at the usual time, give it to him/her as soon as you remember, if you remember on the same day. If not, do not give him/her the missed dose at all. Wait until it is time for your child's next dose. Do not give two doses at once. If you need more information, ask your child's doctor.

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 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), 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, your child's hormone levels will initially increase and then decline over several weeks. During this period, 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.
- 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 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 and sight 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.

Last Revised November 23, 2020