

PART III: CONSUMER INFORMATION

P^rLUPRON[®] leuprolide acetate injection

This leaflet is **PART III** of a three-part Product Monograph published when LUPRON 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. 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 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 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'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 should not be used:

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

What the medicinal ingredient is:

leuprolide acetate

What the important non-medicinal ingredients are:

Each 2.8 mL multiple-dose vial contains **benzyl alcohol**, sodium chloride, and sterile water for injection. Each vial also contains sodium hydroxide and/or acetic acid.

What dosage forms it comes in:

LUPRON is a drug which contains 5 mg of leuprolide acetate per mL. It comes in 2.8 mL multiple-dose vials. LUPRON is supplied as a 14-day kit.

WARNINGS AND PRECAUTIONS

Before your child takes LUPRON tell your child's doctor if:

- Your child is allergic to any component of the medication.
- 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 can cause thinning of the bone and may pose additional risk in patients with such a history.
- Your child has had or is suspected of having seizures, epilepsy, cerebrovascular disorder, central nervous system anomalies, or brain tumor.
- Your child is taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication for depression.

Treatment with LUPRON for central precocious puberty may cause bone loss. This is also called lowered bone mineral density. Once the treatment has ended, this bone loss may stop. Bone density may return to normal levels in late adolescence.

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 needs one injection a day, as prescribed by your child's doctor. The recommended starting dose of LUPRON is 50 mcg/kg/day and can go up to a maximum of 100 mcg/kg/day.

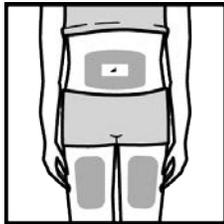
It is very important that the doctor check your child's progress at regular medical visits.

Only a small amount of LUPRON is needed once a day. Use the recommended ½ cc presterilized disposable syringe (see [Instructions for Use leaflet](#)). Syringes are provided in the Patient Administration Kit.

Change the site of injection as instructed by your doctor.

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

SUGGESTED ROTATION OF THE INJECTION SITE



Overdose:

In case of overdose, contact a health care practitioner, hospital emergency department, or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Follow these instructions unless instructed otherwise by your child's doctor: 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. Simply 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Postmarketing reports of convulsions have been observed in patients taking LUPRON. These included patients in the female and pediatric populations, patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and 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 some patients may experience worsening of symptoms.

Some people taking gonadotropin-releasing hormone (GnRH) agonists like LUPRON have had new or worsened mental (psychiatric) problems. Mental (psychiatric) 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: 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 child's 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	
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		✓	

This is not a complete list of side effects. For any unexpected effects while taking LUPRON, contact your doctor or pharmacist.

HOW TO STORE IT

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.

REPORTING SUSPECTED 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 (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, Qc H4S 1Z1 at 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last revised: February 4, 2020

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 injection) 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.

- 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 non-medicinal ingredients in LUPRON DEPOT
- in women who are pregnant or may become pregnant
- in women who are breast-feeding

What the medicinal ingredient is:

leuprolide acetate

What the important non-medicinal ingredients are:

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

What dosage forms it comes in:

LUPRON DEPOT is available in a pre-filled dual-chamber syringe containing leuprolide acetate as sustained-release microspheres and must be reconstituted with a special diluent prior to intramuscular injection. LUPRON DEPOT is available in two strengths: 3.75 and 7.5 mg (1-Month slow release).

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- Your child has had or is suspected of having seizures, epilepsy, cerebrovascular disorder, central nervous system anomalies, or brain tumor.
- Your child is taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication for depression.

Treatment with LUPRON DEPOT for central precocious puberty may cause bone loss. This is also called lowered bone mineral density. Once the treatment has ended, this bone loss may stop. Bone density may return to normal levels in late adolescence.

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**, which must be administered under the supervision of a healthcare provider.

The recommended starting dose of LUPRON DEPOT is:

- 7.5 mg for children weighing ≤ 25 kg
- 11.25 mg for children weighing > 25 to ≤ 37.5 kg
- 15 mg for children weighing > 37.5 kg

The maximum dose is 15 mg per month.

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.

Overdose:

In case of overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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.

Regular injections are important!

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Postmarketing reports of convulsions have been observed in patients taking LUPRON DEPOT. These included patients in the female and pediatric populations, patients with a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and 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.

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		Only if severe	In all cases	
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	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		✓	

Monograph, prepared for health professionals can be found at:

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This leaflet was prepared by AbbVie Corporation.

Last revised: February 4, 2020

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. Protect from freezing.

REPORTING SUSPECTED 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 (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product