

Patient Medication Information for Central Precocious Puberty

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr LUPRON DEPOT®

leuprolide acetate for extended-release injectable suspension

This patient medication information is written for the person who will be taking **LUPRON DEPOT**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LUPRON DEPOT**, talk to a healthcare professional.

What LUPRON DEPOT is used for:

LUPRON DEPOT is for the treatment of children with central precocious puberty.

How LUPRON DEPOT works:

LUPRON DEPOT prevents the brain from releasing gonadotropin releasing hormone (GnRH). This helps stop the progression of puberty. When it's time for normal puberty to start, your healthcare professional can stop treatment with LUPRON DEPOT and normal puberty will begin again.

The ingredients in LUPRON DEPOT are:

Medicinal ingredient: 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 in a pre-filled syringe: 3.75 mg or 7.5 mg leuprolide acetate per 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 you 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.
- has a history of asthma, sinus problems or any allergies.

Other warnings you should know about:

Skin reactions: Very rare, severe allergic skin reactions such as **Stevens-Johnson Syndrome (SJS)** and **Toxic Epidermal Necrolysis (TEN)** have been reported. Some symptoms are a rash with blisters, redness and peeling skin. If you notice these symptoms, tell your healthcare professional right away or get emergency help.

Pseudotumor cerebri (PTC)/idiopathic intracranial hypertension (a condition characterized by increased blood pressure in your head/brain) has been reported in kids receiving this medicine. Monitor/watch your child for signs and symptoms of PTC, including:

- headache
- vision issues such as blurred vision, double vision, loss of vision
- pain behind the eye or pain with eye movement
- ringing in the ears
- dizziness
- nausea

Contact your healthcare professional immediately and take your child to an ophthalmologist (an eye specialist) to find out if there is papilledema (pressure in or around the brain which causes the part of the optic nerve inside the eye to swell). If papilledema is present, this means your child has PTC and immediate treatment is necessary.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take LUPRON DEPOT:

- Your child's healthcare professional will inject LUPRON DEPOT into your child's muscle during scheduled visits.
- It is very important that the healthcare professional checks your child's progress at regular medical visits. **Regular injections are important!**

Usual dose:

The recommended starting dose of LUPRON DEPOT is:

- 7.5 mg per month for children weighing less than 25 kg

- 11.25 mg per month (as one injection each of 3.75 mg and 7.5 mg) for children weighing between 25 kg and 37.5 kg
- 15 mg per month (as two injections of 7.5 mg) for children weighing more than 37.5 kg

The maximum dose is 15 mg per month.

Overdose:

If you think you, or a person you are caring for, have been given too much LUPRON DEPOT, contact your healthcare professional, hospital emergency department, regional poison control centre, or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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 healthcare professional.

Possible side effects from using LUPRON DEPOT:

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

Post-market side effects:

- Seizures (convulsions) in adult patients and children. This includes patients:
 - with a history of seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorders), central nervous system problems or tumors.
 - taking other medicines at the same time such as bupropion and SSRIs. These medicines have been linked with seizures.
 - having seizures without any other conditions.

Other side effects include:

- 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).

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 healthcare professional will want to know about them. Call your child's healthcare professional or tell the healthcare professional 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 healthcare professional.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		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		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Very rare			
Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (severe skin reaction/rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, with a fever, chills, headache, cough, body aches or swollen glands			✓
Unknown			
Hypersensitivity reactions, including anaphylaxis (severe allergic reactions): fever, skin rash, hives, itching, shortness of breath, sudden wheeziness and chest pain or tightness, runny nose, itchy, watery eyes, swelling of eyelids, face, lips, tongue or throat			✓
Pseudotumor cerebri (PTC)/idiopathic intracranial hypertension (a condition characterized by increased blood pressure in your head/brain): Headache, vision issues (such as blurred vision, double vision, loss of vision), pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea.			✓
Injection site necrosis (skin death around injection site): Any sores, changes in skin color or temperature, or severe pain on your skin around injection site.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15 to 25°C. Do not freeze.

Keep out of reach and sight of children.

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 the Patient Medication Information by visiting the Health Canada Drug Product Database website: ([Drug Product Database: Access the database](#) ; the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

Call your healthcare professional to talk about any questions you may have. For questions or concerns visit the manufacturer's website (www.abbvie.ca) or call 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Date of Authorization: 2025-11-13

Patient Medication Information for Prostate Cancer

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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leuprolide acetate for extended-release injectable suspension

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This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LUPRON DEPOT**, talk to a healthcare professional.

Serious warnings and precautions box

LUPRON DEPOT should be prescribed by a healthcare professional experienced with this type of drug.

LUPRON DEPOT may cause:

- worsening of symptoms of prostate cancer at the beginning of the treatment
- bone thinning (osteoporosis)

What LUPRON DEPOT is used for:

LUPRON DEPOT is used in the treatment of advanced prostate cancer.

How LUPRON DEPOT works:

Leuprolide acetate is similar to gonadotropin-releasing hormone (GnRH or LHRH). This is a hormone that is naturally made in your body. Normally, your body releases small amounts of LHRH and this leads to the production of sex hormones. However, when you inject LUPRON DEPOT, sex hormone production is interrupted and testosterone is no longer produced by the testes. When the level of testosterone is decreased in your body, your symptoms will get better.

The ingredients in LUPRON DEPOT are:

Medicinal ingredient: leuprolide acetate

Non-medicinal ingredients: carboxymethylcellulose sodium, D-mannitol, DL-lactic and glycolic acids copolymer (in LUPRON DEPOT 7.5 mg only), glacial acetic acid, polylactic acid (in LUPRON DEPOT 22.5 mg, 30 mg and 45 mg only), polysorbate 80, gelatin (in LUPRON DEPOT 7.5 mg only), stearic acid (in LUPRON DEPOT 45 mg only), and water for injection.

LUPRON DEPOT comes in the following dosage forms:

- Powder in a pre-filled syringe: 7.5 mg (1-Month), 22.5 mg (3-Month), 30 mg (4-Month), and 45 mg (6-Month) leuprolide acetate per 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:

- you are allergic to leuprolide acetate, any similar medications (e.g., histrelin, desorelin), or any of the non-medicinal ingredients in LUPRON DEPOT.

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 you may have, including if you:

- have had or have difficulty urinating due to a block in the urinary tract (obstructive uropathy) and/or a spinal cord tumor (metastatic vertebral lesions).
- have family history of a bone disease (osteoporosis) or are a chronic user of drugs that can reduce bone mass. These 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.
- have had or are suspected of having seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorder), problems with your central nervous system, or a brain tumor.
- are taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any selective serotonin reuptake inhibitor (SSRI) medication. These are used to treat depression.
- have a history of heart disease or disorders, or have a genetic heart condition called “long QT syndrome”.
- have or have a history of high blood sugar (diabetes), high cholesterol, and/or fatty liver. LUPRON DEPOT may affect your blood sugar. Your healthcare professional should do blood tests to check your blood sugar and for metabolic syndrome/changes more often.
- have low red blood cell counts. LUPRON DEPOT may cause a decrease in red blood cells (anemia).
- have problems with your liver.
- have depression or other mental disorders.
- have a history of asthma, sinus problems or any allergies.

During the first few weeks of treatment with LUPRON DEPOT, your symptoms may get worse or you may develop new symptoms. These can include bone pain, neuropathy (tingling, numbness or pain in the affected area) presence of blood in the urine or difficulty urinating.

Other warnings you should know about:

Skin reactions: Very rare, severe allergic skin reactions such as **Stevens-Johnson Syndrome (SJS)** and **Toxic Epidermal Necrolysis (TEN)** have been reported. Some symptoms are a rash with blisters, redness and peeling skin. If you notice these symptoms, tell your healthcare professional right away or get emergency help.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LUPRON DEPOT:

- medicines used to correct heart rhythm such as quinidine, disopyramide, amiodarone, dronedarone, sotalol, dofetilide, ibutilide, flecainide, propafenone
- medicines used to treat schizophrenia such as chlorpromazine
- medicines to treat depression such as amitriptyline, nortriptyline
- morphine-like medicines (e.g., methadone)
- certain antibiotics and antimicrobials such as erythromycin, clarithromycin, azithromycin, moxifloxacin
- antimalarials (e.g., quinine)
- antifungals
- medicines used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery such as ondansetron
- medicines used for the relief of bronchospasm in conditions like asthma and chronic obstructive pulmonary disease such as salbutamol

How to take LUPRON DEPOT:

- Your healthcare professional will inject LUPRON DEPOT into your muscle during your scheduled visits.
- It is very important that your healthcare professional check your progress at regular medical visits.
Regular injections are important!

Usual dose:

- 7.5 mg (1-Month): One injection every month.
- 22.5 mg (3-Month): One injection every three months.
- 30 mg (4-Month): One injection every four months.
- 45 mg (6-Month): One injection every six months.

Overdose:

If you think you, or a person you are caring for, have been given too much LUPRON DEPOT, contact your healthcare professional, hospital emergency department, regional poison control centre, or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss an appointment by a few days, it should not disrupt the benefits of treatment. But you must follow your drug administration schedules for the therapy to be successful.

Possible side effects from using LUPRON DEPOT:

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

Post-market side effects:

- Seizures (convulsions) in adult patients and children. This includes:
 - female patients.
 - patients with a history of seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorders), central nervous system problems or tumors.
 - patients taking other medicines at the same time such as bupropion and SSRIs. These medicines have been linked with seizures.
 - patients having seizures without any other conditions.

Other side effects include:

- low blood pressure (hypotension), high blood pressure (hypertension)
- cardiac arrest (heart stops beating), heart attack (myocardial infarction), sudden cardiac death
- spinal fracture/paralysis
- decreased white blood cell count, decreased red blood cell count
- serious liver injury, fatty liver
- problem with sunlight (photosensitivity reactions)
- inflammation of the tendon (tenosynovitis-like symptoms)
- prostate pain
- a solid swelling of clotted blood within the tissues (hematoma)
- thickening of skin and soft tissue (induration)
- inflammation
- lung problems (interstitial lung disease, pulmonary fibrosis)
- constipation
- trouble sleeping
- back pain
- dizziness

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 healthcare professional 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
- 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 healthcare professional immediately.

Tell your healthcare professional if you develop new or worsened symptoms of depression after beginning LUPRON DEPOT treatment.

A local 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 healthcare professional.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Common			
Decrease in testicular size		✓	
Headache	✓		
Hot flashes		✓	
Impotence/ decrease in libido		✓	
Itching rash		✓	
Skin reactions including reaction at site of injection		✓	
Urinary tract infection (infection in urinary system): Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine, frequent urinating at night		✓	
Uncommon			
Abnormal swelling or numbness of limbs		✓	
Convulsion		✓	
Severe bone pain		✓	
Severe pain in chest or abdomen		✓	
Vision changes		✓	
Very rare			
Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (severe skin reaction/rash): redness, blistering and/or peeling of the skin and/or inside of the			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
lips, eyes, mouth, nasal passages or genitals, with a fever, chills, headache, cough, body aches or swollen glands			
Unknown			
Hypersensitivity reactions, including anaphylaxis (severe allergic reactions): fever, skin rash, hives, itching, shortness of breath, sudden wheeziness and chest pain or tightness, runny nose, itchy, watery eyes, swelling of eyelids, face, lips, tongue or throat			✓
Interstitial lung disease or pulmonary fibrosis (inflammation of the lung): New onset or worsening of shortness of breath, especially with exertion, dry cough/interstitial lung disease, an inflammation of lung tissue		✓	
Serious liver injury: yellow skin, yellow eyes, nausea/vomiting, decreased or loss of appetite, fatigue, itching, abdominal pain and bleeding and bruising			✓
Injection site necrosis (skin death around injection site): Any sores, changes in skin color or temperature, or severe pain on your skin around injection site.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15 to 25°C. Do not freeze.

Keep out of reach and sight of children.

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 the Patient Medication Information by visiting the Health Canada Drug Product Database website: ([Drug Product Database: Access the database](#)); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Date of Authorization: 2025-11-13

Patient Medication Information for Gynecology

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LUPRON DEPOT®**

leuprolide acetate for extended-release injectable suspension

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What LUPRON DEPOT is used for:

Endometriosis:

LUPRON DEPOT 3.75 mg (1-Month) and 11.25 mg (3-Month) is for the **sole treatment** of:

- endometriosis, including pain relief and reducing lesions
- **women close to menopause who do not want surgery:** may relieve symptoms
- **women close to menopause along with surgery:** may relieve symptoms

LUPRON DEPOT 3.75 mg (1-Month) and 11.25 mg (3-Month) is for the **combination treatment with 5 mg norethindrone acetate** for initial treatment or when symptoms return.

Uterine Fibroids (before surgery):

LUPRON DEPOT 3.75 mg (1-Month) is for the **combination treatment with an iron supplement** to improve anemia before surgery for uterine fibroids.

LUPRON DEPOT is not recommended for use in children younger than 18 years of age or women over 65 years of age for the treatment of endometriosis and uterine fibroids.

How LUPRON DEPOT works:

LUPRON DEPOT stops the production of a hormone called gonadotropins from a gland. This decreases estrogen to postmenopausal levels in premenopausal women.

The ingredients in LUPRON DEPOT are:

Medicinal ingredient: leuprolide acetate

Non-medicinal ingredients: carboxymethylcellulose sodium, D-mannitol, DL-lactic and glycolic acids copolymer (only for LUPRON DEPOT 3.75 mg), glacial acetic acid, polylactic acid (only for LUPRON DEPOT 11.25 mg), polysorbate 80, gelatin, and water for injection.

LUPRON DEPOT comes in the following dosage forms:

- Powder in a pre-filled syringe: 3.75 mg or 11.25 mg leuprolide acetate per 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:

- are allergic to leuprolide acetate, any similar medications (e.g., histrelin, desorelin), or any of the other ingredients in LUPRON DEPOT.
- are pregnant or planning to get pregnant.
- have abnormal vaginal bleeding of unknown cause.
- are breast-feeding.

You must use non-hormonal methods of birth control while receiving LUPRON DEPOT.

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 you may have, including if you:

- suspect that you are pregnant.
- are planning to become pregnant.
- take hormonal methods of contraception.
- are breast-feeding.
- have family history of a bone disease (osteoporosis) or are 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.
- have had or are suspected of having seizures, epilepsy, problems with blood flow to your brain (cerebrovascular disorder), problems with your central nervous system, or a brain tumor.
- are taking other medication(s) that have been associated with convulsions or seizures such as bupropion and any SSRI medication. These are used to treat depression.
- may experience an increase in your cholesterol levels during treatment with LUPRON DEPOT.
- have a history of asthma, sinus problems or any allergies.

Other warnings you should know about:

Skin reactions: Very rare, severe allergic skin reactions such as **Stevens-Johnson Syndrome (SJS)** and **Toxic Epidermal Necrolysis (TEN)** have been reported. Some symptoms are a rash with blisters, redness and peeling skin. If you notice these symptoms, tell your healthcare professional right away or get emergency help.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take LUPRON DEPOT:

- Your healthcare professional will inject LUPRON DEPOT into your muscle during your scheduled visits.
- It is very important that your healthcare professional check your progress at regular medical visits.
Regular injections are important!

Usual dose:**Endometriosis:**

If you are taking LUPRON DEPOT 3.7 mg (1-Month), go to your healthcare professional for your injection once every month for 6 months.

If you are taking LUPRON DEPOT 11.25 mg (3-Month), go to your healthcare professional for your injection once every three months for 6 months.

Uterine Fibroids (before surgery):

- 3.75 mg (1-Month) **once a month** for up to 3 months.

For the 3 months you are on LUPRON DEPOT: take an oral iron supplement every day.

Your healthcare professional will tell you how much iron to take every day.

Overdose:

If you think you, or a person you are caring for, have been given too much LUPRON DEPOT, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss an appointment by a few days, it should not disrupt the benefits of treatment. But you must follow your drug administration schedules for the therapy to be successful.

Possible side effects from using LUPRON DEPOT:

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

Signs and symptoms of endometriosis can worsen at the beginning of therapy with LUPRON DEPOT.

Possible common side effects with the use of LUPRON DEPOT include:

- hot flashes, excessive sweats
- gastrointestinal problems, nausea, vomiting
- decreased libido
- muscle or joint pain
- weakness
- breast tenderness/pain and/or vaginitis (infection or inflammation of the vagina)
- emotional changes such as feeling depressed
- headache/migraine
- upset sleep

- nervousness/rapid heartbeat
- edema (swelling, water retention)
- weight gain or loss
- skin reaction at the injection site such as itching, redness, burning, and/or swelling
- acne
- menstrual cramps (dysmenorrhea)

Should these side effects persist or if they are severe, contact your healthcare professional immediately.

Post-market side effects:

- Seizures (convulsions) in adult patients and children. This includes:
 - female patients.
 - patients with a history of seizures, epilepsy, problems with blood flow to the brain (cerebrovascular disorders), central nervous system problems or tumors.
 - patients taking other medicines at the same time such as bupropion and SSRIs. These medicines have been linked with seizures.
 - patients having seizures without any other conditions.

Other side effects include:

- hypotension (low blood pressure)
- peripheral neuropathy (weakness, numbness of the limbs, nerve damage) and spinal fracture/paralysis
- white blood cell count decreased
- liver problems, including serious liver injury
- inflammation of the lung (interstitial lung disease), pulmonary fibrosis (lung disease), dyspnea (difficulty breathing)
- menstrual disorders
- pituitary apoplexy; symptoms include sudden headache, vomiting, visual changes, problem with eye muscle movement (ophthalmoplegia), rash, urticaria (raised red, itchy areas on the skin called hives), tenosynovitis-like symptoms (inflammation of the tendon), altered mental status, and sometimes cardiovascular collapse

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Common			
Headache	✓		
Hot flashes/sweats		✓	
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		✓	
Very rare			
Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) (severe skin reaction/rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, with a fever, chills, headache, cough, body aches or swollen glands			✓
Unknown			
Hypersensitivity reactions, including anaphylaxis (severe allergic reactions): fever, skin rash, hives, itching, shortness of breath, sudden wheeziness and chest pain or tightness, runny nose, itchy, watery eyes, swelling of eyelids, face, lips, tongue or throat			✓
Pulmonary fibrosis or interstitial lung disease (inflammation of the lung): new onset or worsening of shortness of breath or dry cough, often seen with exertion		✓	
Injection site necrosis (skin death around injection site): Any sores, changes in skin color or temperature, or severe pain on your skin around injection site.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 (canada.ca/drug-device-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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15 to 25°C. Do not freeze.

Keep out of reach and sight of children.

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 the Patient Medication Information by visiting the Health Canada Drug Product Database website: ([Drug Product Database: Access the database](#)); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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Instructions for Use
Pr LUPRON DEPOT®
(leuprolide acetate for extended-release injectable suspension)

Powder

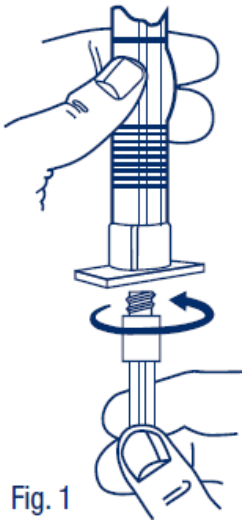
3.75 mg (1-Month), 7.5 mg (1-Month), 11.25 mg (3-Month), 22.5 mg (3-Month), 30 mg (4-Month), and 45 mg/syringe (6-Month) leuprolide acetate per syringe

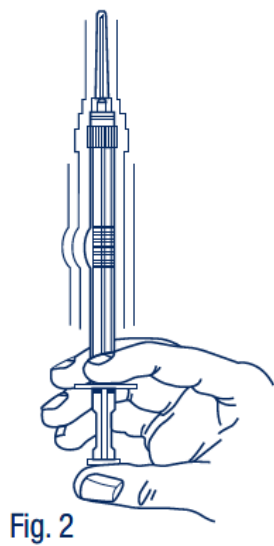
LUPRON DEPOT comes with a special diluent. The powder must be mixed with the diluent before intramuscular injection.

LUPRON DEPOT must be administered by intramuscular injection(s) after reconstitution by a healthcare professional. Due to different release characteristics, a fractional dose of the 3-month, 4-month, or 6-month depot formulation is not equivalent to the same dose of the monthly formulation and should not be given.

The LUPRON DEPOT powder should be visually inspected, and the syringe should not be used if clumping or caking is evident. A thin layer of powder on the wall of the syringe is considered normal. The diluent should appear clear.

Follow the steps below each time you prepare and inject LUPRON DEPOT

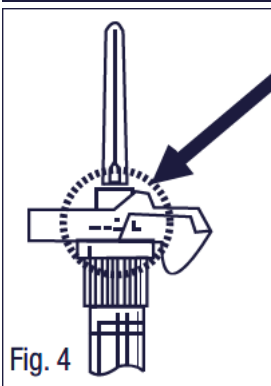
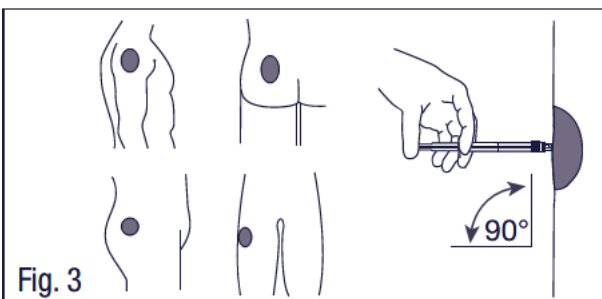
STEP 1  Fig. 1	• To prepare for injection, screw the white plunger into the end stopper until the stopper begins to turn (Fig. 1). • Remember to tighten the needle by twisting the needle cap clockwise. • Do not overtighten.
STEP 2	Holding the syringe upright, release the diluent by slowly pushing (6 – 8 seconds) the plunger until the first stopper is at the blue line in the middle of the barrel

STEP 3

- Keep the syringe upright. Gently shake the syringe to thoroughly mix the microspheres (powder) to form a uniform suspension (Fig. 2).
- The suspension will appear milky. If the microspheres adhere to the stopper or caking/clumping is present, tap the syringe against your finger to disperse.
- Do not use if any of the powder has not gone into suspension.

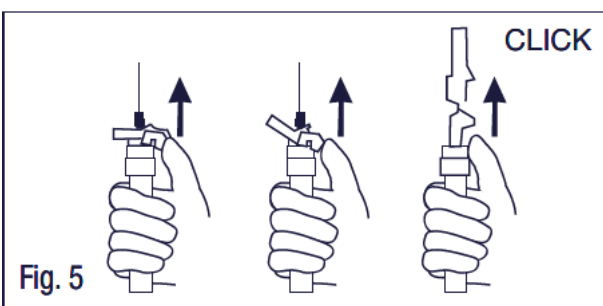
STEP 4

- Keep the syringe upright.
- With the opposite hand, remove the needle cap without twisting and advance the plunger to expel the air from the syringe.

STEP 5

- At the time of reconstitution, inject the entire contents of the syringe intramuscularly by inserting the needle at a 90 degree angle into the gluteal area, anterior thigh, or deltoid; injection sites should be alternated (Fig. 3). The suspension settles very quickly following reconstitution; therefore, **LUPRON DEPOT should be mixed and used immediately.**
- **Note:** Aspirated blood would be visible just below the luer lock connection if a blood vessel is accidentally penetrated. If present, blood can be seen through the transparent LuproLoc® safety device (Fig. 4). If blood is present, remove the needle immediately. Do not inject the medication.

STEP 6



- After injection, withdraw the needle. **Immediately** activate the LuproLoc safety device by pushing the arrow forward with the thumb or finger until the device is fully extended and a CLICK is heard or felt (Fig. 5).

Although the suspension has been shown to be stable for 24 hours following reconstitution, since the product does not contain a preservative, the suspension should be discarded if not used immediately.

As with other drugs administered by injection, the injection site should be varied periodically.

Disposal of syringes should be done according to local requirements.

For questions or concerns, please call 1-888-704-8271.

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