PATIENT MEDICATION INFORMATION FOR CENTRAL PRECOCIOUS PUBERTY

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]LUPRON 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 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 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

Other warnings you should know about:

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 doctor 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 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 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 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 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 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. Postmarking 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		✓	

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	
Vision changes		✓	
UNKNOWN FREQUENCY (reported from postmarketing)			
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.			✓

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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 health 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-

product-database.html; the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

Call your doctor 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.

Last Revised: MAR 30, 2023

PATIENT MEDICATION INFORMATION FOR PROSTATE CANCER

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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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**.

Serious Warnings and Precautions
LUPRON DEPOT should be prescribed by a doctor 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 is LUPRON DEPOT used for?

- LUPRON DEPOT is used in the palliative treatment of prostate cancer. Palliative treatment is the relief of symptoms associated with a disease; it is not a cure.

How does LUPRON DEPOT work?

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.

What are the ingredients in LUPRON DEPOT?

Medicinal ingredients: 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, polysorbate 80, gelatin, and water for injection.

LUPRON DEPOT comes in the following dosage forms:

Powder for suspension: 7.5 mg, 22.5 mg and 30 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:

- 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).
- you 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.
- you 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.
- you 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.
- you have a history of heart disease or disorders, or have a genetic heart condition called “long QT syndrome”.
- you have high blood sugar (diabetes). LUPRON DEPOT may affect your blood sugar and you may need to test your blood sugar more frequently while receiving treatment with LUPRON DEPOT.
- you have low red blood cell counts. LUPRON DEPOT may cause a decrease in red blood cells (anemia).
- you have problems with your liver.
- you have depression or other mental disorders.

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.

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.

The following may interact with LUPRON DEPOT:

- medicines used to correct heart rhythm such as quinidine, disopyramide, amiodarone, dronedarone, sotalol, dofetilide, ibutilide (e.g., Corvert®), flecainide (e.g., Tambocor®), propafenone (e.g., Rythmol®)
- 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 (e.g., Biaxin®), azithromycin (e.g., Zithromax®), moxifloxacin (e.g., Avelox®)
- antimalarials (e.g., quinine)
- antifungals
- medicines used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery such as ondansetron (e.g., Zofran®)
- medicines used for the relief of bronchospasm in conditions like asthma and chronic obstructive pulmonary disease such as salbutamol (e.g., Ventolin®)

How to take LUPRON DEPOT:

- Your doctor or a nurse, will administer LUPRON DEPOT for you during your scheduled visits.
- It is very important that your doctor check your progress at regular medical visits.
- LUPRON DEPOT will be injected into your muscle.
- **Regular injections are important!**
- If you need more information, ask your doctor.

Usual dose:

If you are taking LUPRON DEPOT 7.5 mg (1-Month slow release) go to your doctor or nurse **once every month** for your injection.

If you are taking LUPRON DEPOT 22.5 mg (3-Month slow release), go to your doctor or nurse **once every three months** for your injection.

If you are taking LUPRON DEPOT 30mg (4-Month slow release), go to your doctor or nurse **once every four months** for your injection.

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:

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.

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 female 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. Postmarking reports of cardiac arrest (heart stops beating), low blood pressure (hypotension), heart attack (myocardial infarction), sudden cardiac death, spinal fracture/paralysis, decreased white blood cell count, serious liver injury, problem with sunlight (photosensitivity reactions), inflammation of the tendon (tenosynovitis-like symptoms), prostate pain, a solid swelling of clotted blood within the tissues (hematoma), induration, inflammation, interstitial lung disease, and pulmonary fibrosis 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 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 doctor 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 doctor immediately.

Notify your doctor 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 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			
Decrease in testicular size		✓	
Headache	✓		
Hot flashes		✓	
Impotence/ decrease in libido		✓	
Itching rash		✓	
Skin reactions including reaction at site of injection		✓	
UNCOMMON			
Abnormal swelling or numbness of limbs		✓	
Convulsion		✓	
Severe bone pain		✓	
Severe pain in chest or abdomen		✓	
Vision changes		✓	
UNKNOWN FREQUENCY (reported from postmarketing)			
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		✓	✓

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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 health 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); 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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PATIENT MEDICATION INFORMATION FOR GYNECOLOGY

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]LUPRON 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?

Endometriosis:

LUPRON DEPOT 3.75 mg (1-Month slow release) and 11.25 mg (3-Month slow release) 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 slow release) and 11.25 mg (3-Month slow release) 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 slow release) 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 does LUPRON DEPOT work?

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

What are the ingredients in LUPRON DEPOT?

Medicinal ingredients: 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 for suspension: 3.75 mg and 11.25 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:

- 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.
- You are planning to become pregnant.
- You take hormonal methods of contraception.
- You are breast-feeding.
- You 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.
- You 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.
- You 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.
- You may experience an increase in your cholesterol levels during treatment with LUPRON DEPOT.

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 doctor or a nurse will administer LUPRON DEPOT for you during your scheduled visits.
- LUPRON DEPOT will be injected into your muscle.
- **Regular injections are important!**
- It is very important that your doctor check your progress at regular medical visits.

Usual dose:

Endometriosis:

If you are taking LUPRON DEPOT 3.7 mg (1-Month slow release), go to your doctor or nurse for your injection once every month for 6 months.

If you are taking LUPRON DEPOT 11.25 mg (3-Month slow release), go to your doctor or nurse for your injection once every three months for 6 months.

Uterine Fibroids (before surgery):

- 3.75 mg (1-Month slow release) **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 doctor or pharmacist will tell you how much iron to take every day.

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:

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.

What are 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 doctor immediately.

Side effects reported after the drug was available for sale (postmarketing) include:

- hypotension (low blood pressure)
- convulsion, peripheral neuropathy (weakness, numbness of the limbs, nerve damage) and spinal fracture/paralysis
- white blood cell count decreased
- liver problems, including serious liver injury
- serious allergic reaction (anaphylaxis and anaphylactoid)
- 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			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and 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		✓	
UNKNOWN FREQUENCY (reported from postmarketing)			
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		✓	

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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 health 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Last Revised: MAR 30, 2023

Instructions for Use
PrLUPRON DEPOT®
(leuprolide acetate for depot suspension)

Pre-filled Dual-Chamber Syringe

3.75 mg (1-Month Slow Release)

7.5 mg (1-Month Slow Release)

11.25 mg (3-Month Slow Release)

22.5 mg (3-Month Slow Release)

30 mg (4-Month Slow Release)

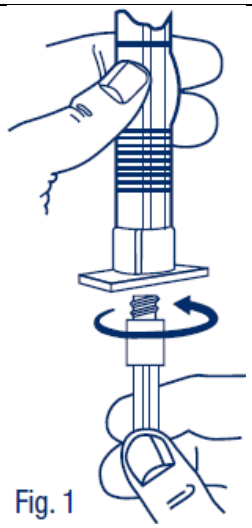
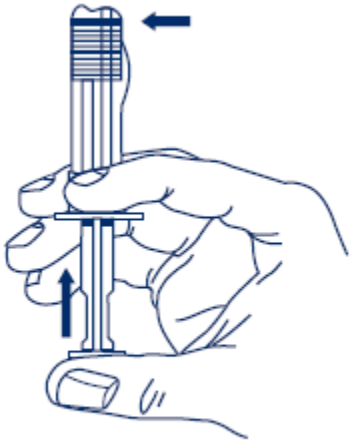
With Sterile Diluent

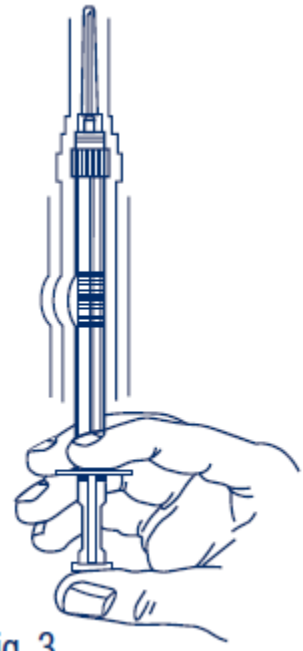
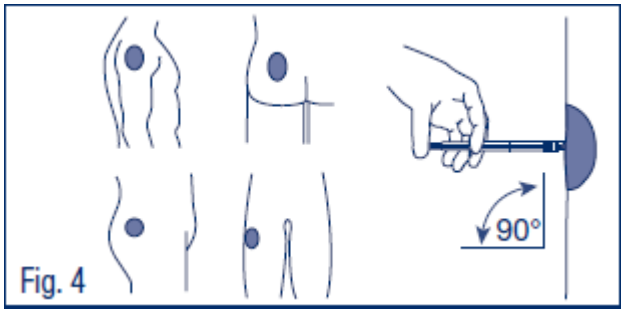
LUPRON DEPOT must be administered by intramuscular injection(s) after reconstitution under the supervision of a healthcare professional. Due to different release characteristics, a fractional dose of the 3-month or 4-month depot formulation is not equivalent to the same dose of the monthly formulation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

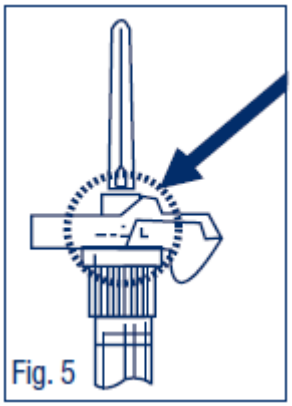
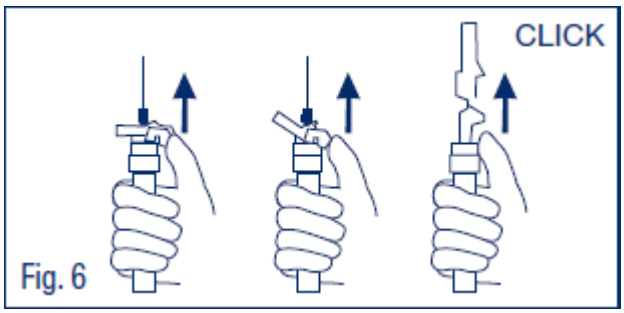
The LUPRON DEPOT powder should be visually inspected, and the syringe should not be used if clumping or caking is evident. A thin layer of powder on the wall of the syringe is considered normal. The diluent should appear clear.

Follow the steps below each time you use LUPRON DEPOT

Prepare for Injection	
STEP 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.

 Fig. 1	
STEP 2  Fig. 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 (Fig. 2).

STEP 3  Fig. 3	• Keep the syringe upright. Gently shake the syringe to thoroughly mix the microspheres (powder) to form a uniform suspension (Fig. 3). • 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  Fig. 4	• 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. 4). 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. 5). 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. 6).

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 regulations/procedures.

Need Help?

Please call 1-888-704-8271:

if you have any questions regarding the drug or this procedure

if the syringe should break or become unusable for any reason and you require a replacement

This leaflet was prepared by AbbVie Corporation.

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