

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr ZEULIDE DEPOT™

Leuprolide acetate for depot suspension

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

Serious Warnings and Precautions

ZEULIDE DEPOT should be prescribed by a healthcare professional experienced in the use of hormonal therapy in prostate cancer.

ZEULIDE DEPOT may cause:

- Worsening of symptoms of prostate cancer at the beginning of the treatment. Higher levels of testosterone can occur during the first week of treatment with ZEULIDE DEPOT. This can cause:
 - Numbness, tingling, weakness or pain in your bones or limbs.
 - bloody urine or blockage in your urinary tract.
 - Pressure on your spinal cord.
 - Kidney problems.
- **Osteoporosis** (bone thinning) and bone fractures can happen while taking ZEULIDE DEPOT. Your healthcare professional will determine if the benefits outweigh the risks.
- **Sudden heart related deaths.** This includes **heart failure, myocardial infarction** (heart attack), stroke, and QT interval prolongation (causes irregular heart rate). Your healthcare professional will determine if the benefits outweigh the risks.
- **Pituitary apoplexy** (bleeding in, or blockage of blood flow to your pituitary gland). This might happen within 2 weeks of the first dose and some within the first hour.
- **Liver injury** caused by drugs. Liver injury and jaundice (yellowing of skin or white of eyes) can happen while taking ZEULIDE DEPOT.

What is ZEULIDE DEPOT used for?

ZEULIDE DEPOT is used to relieve symptoms of prostate cancer that is advanced (cannot be cured) and/or has spread to other parts of the body. The treatment is called palliative because it cannot cure prostate cancer.

How does ZEULIDE DEPOT work?

ZEULIDE DEPOT belongs to a class of drugs called luteinizing hormone-releasing hormone (LH-RH) analogs.

ZEULIDE DEPOT works by lowering the levels of sex-hormones, like testosterone, in the body. This might help relieve some symptoms related to prostate cancer.

What are the ingredients in ZEULIDE DEPOT?

Medicinal ingredients: Leuprolide acetate

Non-medicinal ingredients:

Vial: Mannitol, poly (D, L-lactide-co-glycolide) 50/50 (3.75 mg), polylactic acid (22.5 mg), polysorbate 80, sodium

carboxymethylcellulose, and triethyl citrate.

Syringe: Mannitol and water for injection. May contain hydrochloric acid and/or sodium hydroxide to adjust pH.

ZEULIDE DEPOT comes in the following dosage forms:

- Lyophilized (freeze-dried) powder for injection, 3.75 mg (1-Month) or 22.5 mg (3-Month) leuprolide acetate.
- ZEULIDE DEPOT is supplied in single dose kits containing one vial of lyophilized leuprolide acetate, one prefilled syringe containing 2 mL of diluent, one adaptor system, and one sterile 21 G needle.

Do not use ZEULIDE DEPOT if:

- If you are allergic to leuprolide acetate, any similar LH-RH analogs (e.g., histrelin, desorelin), or any other ingredients in ZEULIDE DEPOT.
- You are a woman, especially if you are or may become. ZEULIDE DEPOT might harm your unborn baby.
- You are a woman that is breastfeeding.
- If you are less than 12 years of age

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

- Have or had urinary tract problems, like a blockage in your urinary tract.
- Have family history of bone problems or are a long-term user of drugs that can lower bone mass such as anticonvulsants (for seizures), corticosteroids (lowers inflammation), alcohol and/or tobacco.
- Have or had heart problems, including a condition called “Long QT syndrome”.
- Have high blood sugar (diabetes).
- Have bleeding disorders, low red blood cell counts (anemia) or low blood platelet counts (thrombocytopenia)
- Are taking anticoagulants (blood-thinner drugs) or antiarrhythmics (heart rhythm drugs).
- Have or had liver and/or kidney problems.
- Have or had depression.

Other warnings you should know about:

ZEULIDE DEPOT can cause serious side effects, including:

- **Convulsions** (muscle spasms or seizures).
- **Behavior and mental status changes:** Depression, mood swings and suicide can happen while taking ZEULIDE DEPOT. Your healthcare professional will talk to you about these mental status problems.
- **Lung and breathing problems:** Chest pain and tightness, coughing up blood, wheezing, strep throat and cold like symptoms can happen while taking ZEULIDE DEPOT.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

Diabetes (high blood sugar):

- There is a higher risk of developing diabetes during treatment with Zeulide Depot.

- Your blood sugar should be monitored during treatment. More frequent monitoring may be needed if you are diabetic.

Anemia (low red blood cell count):

- There is a risk of having low red blood cell counts during treatment with Zeulide Depot.
- Your healthcare professional will determine if the benefits outweigh the risks.

Sexual Health and Fertility:

- Hypogonadism (when your body makes little to no sex hormones) can happen while taking ZEULIDE DEPOT. This can lead to sexual/erectile dysfunction and lower sex drive.

Monitoring and Laboratory Tests:

- You will need blood tests before you start ZEULIDE DEPOT and during your treatment. This will help your healthcare professional know how ZEULIDE DEPOT is affecting your blood, blood sugar levels, hormones and other parts of your body (heart, liver and kidneys).
- You may also get an electrocardiogram (ECG) to see how ZEULIDE DEPOT is affecting your heart rhythm.
- X-rays, ultrasounds and CT scans might be needed to see how ZEULIDE DEPOT is affecting your bone and urinary tract health.

Women and Children:

- ZEULIDE DEPOT is not for use in women or children less than 12 years of age.

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 ZEULIDE DEPOT:

- Medicines that affect your heart rhythm (antiarrhythmic drugs) such as quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, flecainide, propafenone, dronedarone;
- Medicines used to treat mental problems (antipsychotic drugs) such as chlorpromazine;
- Medicines used to treat depression (antidepressant drugs) such as amitriptyline, nortriptyline;
- Narcotic medicines used to treat pain such as methadone;
- Medicines used to treat bacterial infections such as erythromycin, clarithromycin, azithromycin, moxifloxacin;
- Medicines used to treat fungal infections (antifungals);
- Medicines used to treat malaria (antimalarials) such as quinine;
- Medicines used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery such as ondansetron;
- Medicines used to treat breathing problems, like asthma, such as salbutamol.

How to take ZEULIDE DEPOT:

ZEULIDE DEPOT is given to you by a healthcare professional in a healthcare setting.

Usual Dose:

- 3.75 mg: One injection, once a month.
- 22.5 mg: One injection, once every 3 months.

Overdose:

If you think you, or a person you are caring for, have taken too much ZEULIDE DEPOT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of ZEULIDE DEPOT, contact your healthcare professional as soon as possible.
- It is very important that you follow all planned doses of ZEULIDE DEPOT with your healthcare professional.

What are possible side effects from using ZEULIDE DEPOT?

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

In the first few weeks of taking ZEULIDE DEPOT, your testosterone levels will initially increase and then decline over several weeks. During this period some patients may experience worsening of urinary symptoms (difficulty urinating, blood in the urine) and/or a temporary increase in bone pain. Should this occur, contact your doctor immediately.

- general pain, cold or flu-like symptoms
- sore throat
- swelling around the eyesjoint, muscle, pelvic, neck, nipple pain
- feeling tired, weakness
- increased appetite
- loss of taste
- headache
- blurry vision
- trouble sleeping
- diarrhea
- constipation
- stomach pain
- feeling hot or cold
- feeling jittery

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	
VERY COMMON			
Hot flashes		✓	
COMMON			
Anorexia (eating disorder):		✓	
Behavior and mental status changes: agitation including aggressive behavior		✓	

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	
or hostility, depression, emotional and sleep problems			
Bone pain		✓	
Hypogonadism (when your body makes little to no sex hormones): Erectile dysfunction, ejaculation failure, breast swelling/tenderness, low sex drive, testicle problems		✓	
Heavy sweating, cold sweats, night sweats		✓	
Injection Site Reactions: blistering, itching, pain, hives, redness, bruising, hardened skin, skin damage, tenderness, skin bleeding, warmth in the area around the injection	✓		
Lung and breathing problems including pleural effusion (fluid around the lungs): chest pain and tightness, difficult or painful breathing, cough, coughing up blood, wheezing		✓	
Tinnitus: ringing, buzzing, clicking or hissing in the ears	✓		
Vertigo (Light-headedness or dizziness)		✓	
UNCOMMON			
Back pain		✓	
Numbness of limbs		✓	
Persistent nausea or vomiting		✓	
Urinary tract disorders: difficulty and pain when passing urine, exaggerated sense of needing to urinate, blood in urine, urinary tract pain, less urine		✓	
UNKNOWN FREQUENCY			
Allergic reaction: Chest tightness, difficulty breathing, chest pain, sneezing, coughing			✓
Liver Disorder/Injury: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, fever, fatigue, weakness		✓	
Osteoporosis (thin, fragile bones): broken bones, pain, back pain that gets worse when standing or walking		✓	
Heart Failure, Myocardial Infarction (heart attack): crushing chest pain, shortness of breath, sweating, nausea,			✓

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	
pain in the jaw, neck and/or arm, irregular heartbeat, fluid retention, swelling in legs, ankles and feet, fluid retention			
Pituitary Apoplexy (bleeding in, or blockage of blood flow to your pituitary gland): sudden headache, vomiting, visual changes,			✓
Convulsions (seizures, muscle spasms)			✓
Weakness, numbness, tingling and/or pain in the arms, hands, legs or feet		✓	

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:

- ZEULIDE DEPOT must be kept below 25°C. Protect from freezing.
- ZEULIDE DEPOT will be managed and stored by healthcare professionals.
- Keep out of reach and sight of children.

If you want more information about ZEULIDE 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.veritypharma.com, or by calling 1-800877-4414.

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