

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Dispensing this medicine requires a doctor's prescription

**Decapeptyl Depot
11.25 mg
Powder and solvent for
reconstituting a suspension for
intramuscular injection**

Composition:
Each vial of Decapeptyl Depot 11.25 mg contains 11.25 mg triptorelin (as embonate).
Inactive ingredients: See Section 6 'Additional Information'.
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.
This medicine is intended for use in adults only.

- 1. What is this medicine intended for?**
This medicine is intended
- for treating advanced hormone-dependent prostate cancer
 - lowering sexual hormones level
- Therapeutic group:** long-term analog of GnRH (gonadotropin releasing hormone)
- 2. Before using this medicine**

Do not use this medicine:

- If you are sensitive (allergic) to triptorelin, other analogs of the gonadotropin releasing hormone (GnRH is also called LHRH), or to any of the other ingredients that this medicine contains (see Section 6).
- In cases of spinal cord metastases.
- This medicine is not intended for patients with non-hormone dependent prostate cancer or in cases of surgical castration.

- Special warnings about using this medicine**
Before using this medicine, tell your doctor if:
- you are depressed. There have been reports of depression, which may be serious, among patients taking Decapeptyl Depot.
 - you are using anticoagulants, because you may get a bruise at the injection site.
 - you are a heavy drinker, a smoker, have osteoporosis or have a family history of osteoporosis (a condition that weakens your bones), have a poor diet or take medicines (for example anticonvulsants, steroids). When Decapeptyl Depot is used for a long period of time the risk of developing weak bones is increased, especially if any of the above applies.
 - you have any heart or blood vessel disease, including heart rhythm disorders (arrhythmia), or are taking medicines for these diseases. The risk of heart rhythm disorders may be increased while using Decapeptyl Depot.
 - you have diabetes, or a heart or blood vessel problem.
- During the course of this treatment***
- Allergic reactions: In rare cases, severe allergic reactions have been observed within a short time after injection (see the section 'Side effects'). In such cases, get medical help immediately. Paresthesia (prickling) and severe migraine are rare. Stop taking this treatment if these effects recur or are severe.
 - When you start this treatment the amount of testosterone in your body will go up. This could make your cancer symptoms worse. If this happens, consult your doctor. Your doctor may give you a medicine (anti-androgen) to prevent the symptoms from getting worse.
 - Like other GnRH analogs, during the first weeks of treatment, Decapeptyl Depot may in some few cases cause pressure on the spinal cord or blockage of the urethra (exit pipe of urine from the body). Your doctor will monitor your condition and treat you accordingly, if necessary.
 - If you undergo tests for function of the pituitary during the course of treatment or

- after stopping treatment with Decapeptyl Depot, the results may be misleading.
- If you have an enlarged pituitary (benign tumor) that you were not aware of, it may be discovered during the course of treatment with Decapeptyl Depot. The symptoms include sudden headaches, vomiting, vision problems, and paralysis of eye muscles. In such cases, get medical help immediately.
- Tests and follow-up**
During the treatment, your doctor may order blood tests to monitor how well your treatment is working.
- Other medicines and Decapeptyl Depot 11.25 mg**
If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.
Particularly if you are taking:
- anticoagulants
 - medicines that affect heart rate, and which are known to prolong the QT interval, such as: quinidine, disopyramide or amiodarone, sotalol
 - medicines that affect hormone secretion from the pituitary.
- Pregnancy and breastfeeding:**
Do not use this medicine if you are pregnant or breastfeeding.
- Driving and using machines:**
Certain side effects of this medicine such as apathy, epileptic seizures, and impaired vision, may affect your reactions and impair your ability to drive and use tools and machines.
- 3. How to use this medicine?**
Always use according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how you should take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
The recommended dose is usually one injection every three months.
A doctor or nurse will inject the medicine into your muscle.
Do not exceed the recommended dose.

- If you have injected an overdose, or if a child has accidentally swallowed some medicine,** see a doctor immediately or go immediately to a hospital emergency room and bring the medicine package with you.
If you forget to get an injection at the required time (every three months) consult your doctor. Persist with the treatment as recommended by the doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.
Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.
- 4. Side effects**
Like all medicines, taking Decapeptyl Depot 11.25 mg may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them. See a doctor immediately if you have difficulty swallowing or breathing, swelling of the lips, face, throat, or tongue, a rash. These can be signs of an allergic reaction.
If you experience any of the symptoms of a pituitary apoplexy (rare): sudden headache, vomiting, vision problems, paralysis of eye muscles, changes in your mental state, and occasionally collapse of the heart and blood vessel system contact your doctor immediately!
- Additional side effects:**
Rise in lymphocyte count (white blood cells) has been reported among patients who were treated with a GnRH analog.
Very common side effects – affect more than one in ten users
- hot flushes, flushed face (particularly when starting treatment)
 - reduced size of genitals
 - impotence, reduced libido
 - bone pain
- Common side effects – affect 1-10 in 100 users**
- dizziness, headache, insomnia
 - depression, mood swings

- urinary tract infection
 - temporary tumor flare
 - decreased appetite
 - increased concentration of the enzyme alkaline phosphatase, increased concentration of uric acid
 - eye pain, conjunctivitis
 - increased blood pressure
 - cough, shortness of breath, sore throat
 - nausea, stomach ache, constipation, diarrhea, dyspepsia
 - liver function disorders
 - rash
 - back ache, muscle and joint pain, pain in arms and legs, muscle cramps in lower limbs
 - problems passing urine, urinary retention
 - enlarged breasts in men, breast pain
 - pain, fatigue, weakness, chest pain, redness, bruises and/or pain at the injection site, edema (liquid builds up in body tissue)
- Uncommon side effects - affect 1-10 in 1000 users**
- ringing in your ears
 - tingling or numbness
 - anemia
 - signs of hypersensitivity (allergy)
 - increase in blood sugar levels (hyperglycemia)
 - increase in nitrogen levels in your blood and urine
 - diabetes
 - weight gain
 - irritability, memory loss, feeling euphoric
 - drowsiness, loss of consciousness
 - low blood pressure
 - deep vein thrombosis
 - pulmonary embolism
 - runny nose
 - vomiting, frequent bowel movements, gastro-esophageal reflux
 - jaundice
 - excessive sweating, hair loss, itch, eczema, severe acne
 - osteoarthritis (degenerative joint inflammation)
 - muscle weakness
 - urinating more frequently, urinating at night, bladder disorders, incontinence, kidney pain, blood in your urine, abnormal kidney function
 - functional disorders of the prostate and

- testicles, breast inflammation
 - discomfort, complications from surgery get worse
- Rare and very rare side effects - affect 1-10 (rare) or less than one (very rare) in 10,000 users**
- lymphadenopathy (inflammation of the lymph nodes)
 - migraine
 - alterations in sense of taste, reduced sense of touch, convulsions, spinal cord compression (very rare)
 - vision disorders
 - myocardial ischemia (blocked blood vessels in the heart muscle)
 - urticaria (allergic inflammation of the skin)
 - sensitivity to light
 - pathological fractures
 - pain in the perineum (pain in the area between the testicles and the anus)
- If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**
Reporting side effects
You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects, or by clicking the link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>
- 5. How to store the medicine?**
Prevent poisoning! To prevent poisoning, keep this and all other medicines, in a closed place out of the reach and sight of children and/or infants.
Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Storage conditions
Store below 25°C, use the reconstituted suspension immediately after preparing it.

- 6. Additional information**
In addition to the active ingredient the powder also contains:
poly (d,l-lactide-co-glycolide), mannitol, carmellose sodium, polysorbate 80.
Composition of the solvent: water for injection.
What the medicine looks like and what are the contents of the package:
This medicine is a powder and solvent for preparing a slow-release suspension for injection. The powder is white to creamy and the solvent is a clear solution.
The medicine package contains one vial with powder, one ampule with solvent, in addition the package contains a syringe and two needles.
License holder name and address:
Ferring Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park, Caesarea 3088900
Manufacturer name and address:
Debiopharm Research & Manufacturing S.A., Martigny, Switzerland
This leaflet was reviewed and approved by the Ministry of Health in August 2017, and revised in October 2019 in accordance with Ministry of Health guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 135-83-31300