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

This medicine is dispensed with a doctor's prescription only

Decapeptyl Depot 11.25 mg

Powder and solvent for reconstituting a suspension for intramuscular injection

Active ingredient

Each vial of Decapeptyl Depot 11.25 mg contains 11.25 mg triptorelin (as embonate).

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional Information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult 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 analogue of GnRH (gonadotropin releasing hormone)

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to triptorelin embonate, gonadotropin releasing hormone (GnRH), other analogues of the gonadotropin releasing hormone (GnRH is also called LHRH), or to any of the other ingredients that this medicine contains (see section 6).

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. Your doctor may want to monitor your condition during treatment.
- if you are using anticoagulants, because you may get a bruise at the injection site.
- In adults, treatment with Decapeptyl Depot may cause weakening of the bones (osteoporosis) and an increased risk of fractures. Tell your doctor if you have any of the risk factors listed below as he/she might prescribe you treatment with bisphosphonates (drugs used to treat a decline in bone density). Risk factors may include:
  - If you or any of your close family have weakening of the bones (osteoporosis).
  - If you drink excessive amounts of alcohol and/or smoke heavily.
  - If you take medicines over a long period of time that cause thinning of the bones, for example medicines for epilepsy or steroids (such as hydrocortisone or prednisolone).
- if 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.
- if you have diabetes, or a heart or blood vessel problem.
- if you have been surgically castrated, triptorelin will not cause any further decrease in testosterone levels and therefore should not be used.

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. In rare cases of paraesthesia (prickling) and severe migraine, 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 analogues, during the first weeks of treatment, Decapeptyl Depot may cause symptoms due to compression of the spinal cord (e.g. pain, numbness or weakness of legs) or blockage in the urethra (exit pipe of urine from the body). If you feel any of these symptoms, contact your doctor immediately. Your doctor will check your condition and treat you accordingly.
- The results of tests for function of the pituitary gland or sex organs during the course of treatment or after stopping treatment with Decapeptyl Depot may be misleading.
- If you have an enlarged pituitary (benign tumour) 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.
- Testosterone decreasing medicines may cause changes in ECG associated with heart rhythm disorders (QT prolongation).
- Treatment with GnRH analogues including Decapeptyl depot might increase the risk of anaemia (defined as a decrease in the count of red blood cells).

Children and adolescents

Decapeptyl Depot 11.25 mg is not intended for use in neonates, children and adolescents.

Tests and follow-up

Your doctor may instruct you to perform blood tests during the treatment to monitor treatment efficacy.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Decapeptyl Depot might interfere with the activity of medicines used to treat heart rhythm disorders (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm disorders when administered in combination with other medicines (e.g. methadone, used for pain relief and as a treatment of addictions, moxifloxacin (an antibiotic), antipsychotics for treatment of serious mental illnesses).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or planning to become pregnant, consult your doctor before taking medicines.

Do not use this medicine if you are pregnant or breastfeeding.

Driving and using machines:

Decapeptyl Depot 11.25 may change your reactions to such an extent that the ability to drive and operate machines is impaired. This is particularly true in combination with alcohol. You may feel dizzy, tired or experience problems such as blurred vision. These effects may be possible side effects of the treatment or due to the disease itself. If you feel any of these side effects, do not drive or use machines.

Important information about some of this medicine's ingredients

This medicine contains less than 1 mmol (23 mg) sodium per dose that is to say it is essentially "sodium-free".

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage 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, immediately see a doctor or go 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.

Adhere to the treatment as recommended by your 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 every time you take 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 with all medicines, using Decapeptyl Depot 11.25 mg may cause side effects in some users. 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 or angioedema which has been reported in rare cases (may affect up to 1 in 1,000 people).

Additional side effects:

As with other GnRH agonist therapies or after surgical castration, the most commonly observed side effects due to triptorelin treatment are due to its expected pharmacological activity. These effects include hot flushes and decreased libido.

Rise in lymphocyte (white blood cells) count has been reported among patients treated with a GnRH analogue.

With the exception of immuno-allergic reactions and injection site reactions, all side effects are known to be related to changes in testosterone level.

Very common side effects – affect more than one in ten users

- hot flushes
- weakness
- excessive sweating
- back pain
- pins and needles sensation in the legs
- reduced libido
- impotence

Common side effects – affect 1-10 in 100 users

- nausea, dry mouth
- pain, bruises, redness and swelling at injection site, muscle and bone pain, pain in the arms and legs, oedema (build up of fluid in the body tissues), lower abdominal pain
- high blood pressure
- allergic reaction
- increase in weight
- dizziness, headache
- loss of libido, depression, mood swings

Uncommon side effects - affect 1-10 in 1,000 users

- increase in blood platelets
- palpitations
- ringing in the ears, vertigo, blurred vision
- pain in abdomen, constipation, diarrhoea, vomiting
- drowsiness, severe shivering associated with sweating and a fever, sleepiness, pain
- change in blood tests (including elevated liver enzymes), increase in blood pressure
- weight loss
- loss of appetite, increase of appetite, gout (severe pain and swelling in the joints usually in the big toe), diabetes, excessive lipids in the blood
- joint pain, muscle cramps, muscle weakness, muscle pain, swelling and tenderness, bone pain
- tingling or numbness
- inability to sleep, irritability
- enlarged breasts in men, breast pain, reduction in testicular size, pain in testicles
- difficulty in breathing
- acne, hair loss, itching, rash, redness of skin, hives
- urination at night, problems passing urine
- nosebleeds

Rare side effects – affect 1-10 in 10,000 users

- red or purple spots on the skin
- abnormal sensation in the eye, blurring or disturbance in vision
- sensation of fullness in the abdomen, flatulence, taste disorders
- chest pain
- difficulty in standing
- flu-like symptoms, fever
- inflammation of the nose/throat
- increased body temperature
- stiff and swollen joints, muscular stiffness, osteoarthritis
- memory loss
- feeling confused, decreased activity, having a feeling of elation and feeling good
- shortness of breath when lying flat
- blisters
- low blood pressure

Side effects of unknown frequency (the frequency of these side effects has not been established yet)

- changes in ECG (QT prolongation)
- general feeling of discomfort
- anxiety
- urinary incontinence
- in the event of a pituitary tumour, an increased risk of bleeding in this area
- Anaemia (decrease in the count of red blood cells)

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 by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.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) which is stated 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 contents of the pack:

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.

Registration holder's name and address:

Ferring Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park, Caesarea 3088900

Manufacturer's name and address: Debiopharm Research & Manufacturing S.A., Switzerland

This leaflet was revised in February 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 135-83-31300