ELIGARD® 22.5 mg powder and solvent for solution for injection

leuprorelin acetate

IE6036001P99-A1.0

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. WHAT ELIGARD IS AND WHAT IT IS USED FOR

The active substance of ELIGARD belongs to the group of so-called gonadotropin releasing hormones. These medicines are used to decrease the production of certain sex hormones (testosterone).

ELIGARD is used to treat hormone dependent metastatic **prostate cancer** in adult men and for the treatment of high-risk non-metastatic hormone dependent prostate cancer in combination with radiotherapy.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ELIGARD

Do not use ELIGARD
- If you are a **woman or a child**
- If you are **hypersensitive (allergic)** to the active substance leuprorelin acetate, products with an activity comparable to the naturally occurring hormone gonadotropin, or to any of the other ingredients of ELIGARD (listed in section 6).
- Following **surgical removal of your testes,** as in that case ELIGARD does not lead to a further decrease in serum testosterone levels.
- As the only treatment if you suffer from symptoms related to pressure on the spinal cord or tumour in the spinal column. In this case, ELIGARD may only be used in combination with other medicinal products for prostate cancer.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using ELIGARD
- If you have any of the following: Any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using ELIGARD.
- If you have **difficulties urinating.** You should be monitored closely during the first weeks of treatment.
- If **pressure on the spinal cord or difficulties with urinating develops.** In connection with other drugs having a similar mechanism of action like ELIGARD, it has been reported that severe cases of pressure effects on the spinal cord and narrowing of the tubes between the kidneys and the urinary bladder may contribute to paralysis like symptoms. If these complications develop, standard therapy should be started.
- If you experience sudden headache, vomiting, altered mental status and sometimes heart collapse, within two weeks of taking ELIGARD, then alert the doctor or medical staff. These are rare cases termed as pituitary apoplexy, which have been reported IN OTHER DRUGS which have a mechanism similar to ELIGARD.
- If you suffer from **diabetes mellitus** (elevated blood sugar levels). You should be regularly monitored during treatment.
- Treatment with ELIGARD can increase the risk for fractures due to osteoporosis (decrease in bone density).
- There have been reports of depression in patients taking ELIGARD. If you are taking ELIGARD and develop depressed mood, inform your doctor.
- There have been reports of cardiovascular events in patients taking products similar to ELIGARD of which it is unknown if it is related to these products. If you are taking ELIGARD and develop cardiovascular signs or symptoms, inform your doctor.
- There have been reports of seizures in patients after administration of ELIGARD. If you are taking ELIGARD and develop seizures, inform your doctor.
- If you suffer from a bad or recurrent headache, problems with your eyesight and ringing or buzzing in the ears contact your doctor immediately.

Initial treatment complications
During the first week of treatment, there is generally a brief increase in the male sex hormone testosterone in the blood. This can lead to a temporary worsening in the disease-related symptoms and also to the occurrence of new symptoms that have not been experienced up to this point. These especially include bone pain, urination disturbances, pressure on the spinal cord, or the secretion of blood in the urine. These symptoms usually subside on continuation of treatment. If the symptoms do not subside, you should contact your doctor.

If ELIGARD does not help
A proportion of the patients will have tumours, which are not sensitive to decreased serum testosterone levels. Please talk to you doctor if you have the impression that the effect of ELIGARD is too weak.

Other medicines and ELIGARD
ELIGARD might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses). Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
ELIGARD is not intended for women.

Driving and using machines
Fatigue, dizziness and visual disturbances are possible side effects of the treatment with ELIGARD or might be a result from the disease. If you suffer from these side effects, take care when driving or operating machines.

3. HOW TO USE ELIGARD

Dose
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If not otherwise prescribed by your doctor, ELIGARD 22.5 mg is administered **once** every **three months.**

The injected solution forms an active substance depot from which a continuous release of the active substance leuprorelin acetate takes place over a period of three months.

Additional tests
Response to therapy with ELIGARD should be checked by your doctor by means of checking specific clinical values and by measuring the blood levels of the so-called prostate-specific antigen (PSA).

Method of administration
ELIGARD should only be administered by your **doctor** or a **nurse** who will also take care of the preparation of the product.

After preparation, ELIGARD is administered as a subcutaneous injection (injection into the tissue below the skin). Intra-arterial (into an artery) or intravenous (into a vein) injection has to be strictly avoided. As with other active substances that are injected subcutaneously, the site of injection should be varied periodically.

If you receive more ELIGARD than you should
Since the injection is generally administered by your doctor or appropriately trained staff, over dosage is not to be expected.
If a larger amount than intended is nevertheless administered, your doctor will monitor you specifically and give you additional treatment as required.

If the administration of ELIGARD is forgotten
Please talk to you doctor if you believe that your three monthly administration of ELIGARD was forgotten.

Effects when the treatment with ELIGARD is stopped
As a general rule, the therapy of prostate cancer with ELIGARD requires long-term treatment. Therefore, therapy should not be terminated, even if there is an improvement in the symptoms or if they disappear completely.

If the treatment with ELIGARD is stopped prematurely, a deterioration of disease-related symptoms can occur.

You should not stop the therapy prematurely without previously consulting your doctor.

If you have any further question on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ELIGARD can cause side effects, although not everybody gets them.

Side effects that have been observed during treatment with ELIGARD are mainly attributable to the specific effect of the active substance leuprorelin acetate, namely the increase and decrease of certain hormones. The most commonly described side effects are hot flashes (approximately 58% of patients), nausea, malaise and fatigue, as well as temporary local irritations at the site of injection.

Initial side effects
During the first weeks of treatment with ELIGARD, disease-specific symptoms may worsen, because in the first instance there is generally a brief increase in the male sex hormone testosterone in the blood. Therefore, your doctor may administer an appropriate anti-androgen (substance that inhibits the effect of testosterone) at the initial phase of the treatment in order to reduce possible after-effects *(See also Section 2 Before you use ELIGARD, Initial treatment complications).*

Local side effects
Local side effects that have been described after the injection of ELIGARD are typically those, which are often associated with similar subcutaneously injected preparations (preparations which are injected into the tissue below the skin). Mild burning immediately after the injection is very common. Stinging and pain after the injection are common, as well as a bruise at the injection site. Redness of the skin at the injection site has been reported commonly. Tissue hardening and ulceration are uncommon.

These local side effects following subcutaneous injection are mild and described as being of brief duration. They do not occur again in between the individual injections.

Very common side effects (may affect more than 1 in 10 people)
- Hot flashes
- Spontaneous bleeding in skin or mucous membrane, redness of the skin
- Fatigue, injection-related side effects *(see also local side effects above)*

Common side effects (may affect up to 1 in 10 people)
- Nasopharyngitis (symptoms of common cold)
- Nausea, malaise, diarrhoea, inflammation of the stomach and intestines (gastroenteritis/colitis)
- Itching, nightly sweating
- Pain in the joints
- Irregular trips to the toilet to pass water (also at night), difficulty in starting to pass water, painful urination, reduced urine output
- Breast tenderness, swelling of the breast, shrinking of testicles, testicular pain, infertility, erectile dysfunction, reduced penis size
- Rigors (episodes of exaggerated shaking with high fevers), weakness
- Prolonged bleeding time, changes in blood values, decreased red blood cells/low red blood cell count

Uncommon side effects (may affect up to 1 in 100 people)
- Urinary tract infection, local skin infection
- Worsening of diabetes mellitus
- Abnormal dreams, depression, decreased libido
- Dizziness, headache, an alteration in the skin sensation, insomnia, taste disturbance, smell disturbance
- Hypertension (increased blood pressure), hypotension (decreased blood pressure)
- Shortness of breath
- Constipation, dry mouth, dyspepsia (disturbed digestion, with symptoms as full stomach, pain in the stomach, belching, nausea, vomiting, burning feeling in the stomach), vomiting
- Clamminess, increased sweating
- Back pain, muscle cramps
- Haematuria (blood in the urine)
- Bladder spasm, more trips to the toilet to pass water than usual, unable to pass water
- Enlargement of male breast tissue, impotence
- Lethargy (sleepiness), pain, fever
- Increased weight
- Loss of balance, light-headedness
- Muscle wasting/loss of muscle tissue after prolonged use

Rare side effects (may affect up to 1 in 1,000 people)
- Abnormal involuntary movements
- Sudden loss of consciousness, fainting
- Flatulence, belching
- Hair loss, skin eruption (pimples on the skin)
- Breast pain
- Injection site ulceration

Very rare side effects (may affect up to 1 in 10,000 people)
- Injection site necrosis

Not known (frequency cannot be estimated from the available data)
- Changes in ECG (QT prolongation)
- Inflammation of lungs, lung disease
- Idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms and ringing or buzzing in one or both ears)

Other side effects
Other side effects that have been described in the literature in relation with treatment with leuprorelin, the active substance of ELIGARD, are oedema (accumulation of fluid in tissue, appearing as swelling of the hands and feet), pulmonary embolism (resulting in symptoms like breathlessness, difficulty in breathing and chest pain), palpitations (awareness of your heartbeat), muscle weakness, chills, rash, impaired memory and impaired vision. Increasing signs of a decrease in bone tissue (osteoporosis) may be expected after long-term treatment with ELIGARD. Due to osteoporosis, the risk for fractures increases.

Serious allergic reactions, which cause difficulty in breathing or dizziness, have been reported rarely after administration of products in the same class as ELIGARD.

Seizures have been reported after administration of products in the same class as ELIGARD.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ELIGARD

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Storage instructions
Store in a refrigerator (2°C - 8°C).
Store in the original package in order to protect from moisture.

This product must be at room temperature prior to injection. Remove from the refrigerator approximately 30 minutes before use. Once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to four weeks.

Once the tray has been opened, the product must be prepared straight away and the product must be used immediately. For single use only.

Instructions on disposal of unused or expired ELIGARD packs
Do not throw away any medicines via wastewater or household waste.
Ask your pharmacist how to throw away medicines you no longer use.
These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ELIGARD contains
The active substance is leuprorelin acetate.
One pre-filled syringe (Syringe B) contains 22.5 mg leuprorelin acetate.

The other ingredients are Poly(DL-lactic-co-glycolic-acid) (75:25) and N-methyl-2-pyrrolidone in the pre-filled syringe with solution for injection (Syringe A).

What ELIGARD looks like and contents of the pack
ELIGARD is a powder and solvent for solution for injection.
ELIGARD 22.5 mg is available in:
- A thermoformed tray pack and a 20-gauge sterile needle in a cardboard carton. The tray contains a desiccant pouch and a pre-connected syringe system consisting of:
  - syringe A pre-filled with the solvent
  - syringe B pre-filled with the powder
  - connector with latching button for syringe A and B.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Eligard Depot 22.5 mg
Belgium: Depo-Eligard 22.5 mg
Bulgaria: Eligard 22.5 mg
Cyprus: Eligard
Czech Republic: Eligard
Denmark: Eligard
Estonia: Eligard
Finland: Eligard
France: Eligard 22.5 mg
Germany: Eligard 22.5 mg
Hungary: Eligard 22.5 mg
Iceland: Eligard
Ireland: Eligard 22.5 mg
Italy: Eligard
Latvia: Eligard 22.5 mg
Lithuania: Eligard 22.5 mg
Luxembourg: Depo-Eligard 22.5 mg
Netherlands: Eligard 22.5 mg.
Norway: Eligard
Poland: Eligard 22.5 mg
Portugal: Eligard 22.5 mg
Romania: Eligard 22.5 mg
Slovakia: Eligard 22.5 mg
Slovenia: Eligard 22.5 mg
Spain: Eligard Trimestral 22.5 mg
Sweden: Eligard

Product procured from within the EU by the Parallel Product Authorisation Holder: Originalis B.V., Joop Geesinkweg 901, 1114 AB Amsterdam-Duivendrecht, The Netherlands.

Manufacturer:
Recordati Industria Chimica e Farmaceutica S.p.A,
Via Matteo Civitali 1
20148 Milano
Italy

Repackaged by:
Originalis B.V., Diamantweg 4, 1812RC Alkmaar, The Netherlands.

Parallel Product Authorization Number:
ELIGARD 22.5 mg powder and solvent for solution for injection - PPA2306/036/001

Eligard® is a registered trademark of Tolmar International Limited

This leaflet was last revised in 09/2024.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Write to info@originalis.eu
to obtain the leaflet in a format suitable for you.**

The following information is intended for healthcare professionals only:

**Allow the product to come to room temperature by removing from the refrigerator approximately 30 minutes prior to use.
Please prepare the patient for injection first, followed by the preparation of the product, using the instructions below. If the product is not prepared using the proper technique, it should not be administered as lack of clinical efficacy may occur due to incorrect reconstitution of the product.**

Step 1
On a clean field, open the tray by tearing off the foil from the corners to remove the contents. Discard the desiccant pouch. Remove the pre-connected syringe system (Figure 1.1) from the tray. Open the safety needle package (Figure 1.2) by peeling back the paper tab. **Note:** Syringe A and Syringe B should not be lined-up yet.

Figure 1.1
Tray Contents: pre-connected syringe system

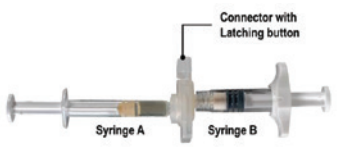
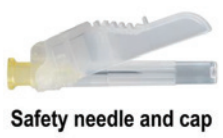
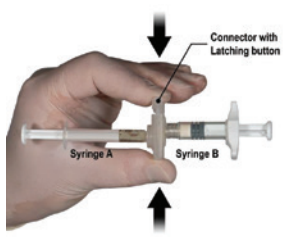


Figure 1.2
Under the Tray: safety needle and cap



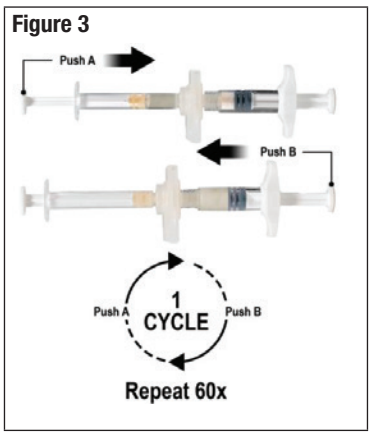
Step 2
Grasp the latching button on the connector with your finger and thumb and press (Figure 2) until you hear a snapping sound. The two syringes will be lined up. No particular orientation of the syringe system is required to activate the connector. Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).

Figure 2



Step 3
Holding the syringes in a horizontal position, transfer the liquid contents of Syringe A into the leuprorelin acetate powder contained in Syringe B. Thoroughly mix the product for 60 cycles by gently pushing the contents of both syringes back and forth between both syringes (a cycle is one push of the plunger for Syringe A and one push of the plunger for Syringe B) in a horizontal position to obtain a homogenous, viscous solution (Figure 3). Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).

Figure 3



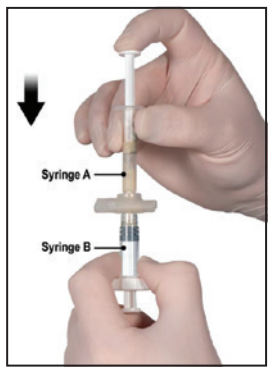
When thoroughly mixed, the viscous solution will appear with a colour in the range of colourless to white to pale yellow (which could include shades of white to pale yellow).

**Important: After mixing proceed with the next step immediately as the product gets more viscous over time.
Do not refrigerate the mixed product.**

Please note: Product must be mixed as described; shaking WILL NOT provide adequate mixing of the product.

Step 4
After mixing, hold the syringes vertically with Syringe B on the bottom. The syringes should remain securely coupled. Draw the entire mixed product into Syringe B (short, wide syringe) by pushing down the Syringe A plunger and slightly withdrawing the Syringe B plunger (Figure 4).

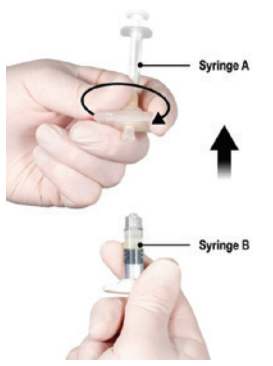
Figure 4



Step 5
While ensuring Syringe A plunger is fully pushed down, hold the connector and unscrew it from Syringe B. Syringe A will remain attached to the connector (Figure 5). Ensure that no product leaks out as the needle will then not secure properly when attached.

Please note: one large or a few small air bubbles may remain in the formulation - this is acceptable. **Please do not purge the air bubbles from Syringe B at this stage as product may be lost!**

Figure 5



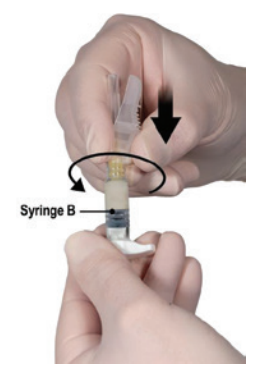
Step 6
- Hold Syringe B upright and hold back the white plunger to prevent loss of the product.
- Secure the safety needle to Syringe B by holding the syringe and gently turning the needle clockwise with approximately a three-quarter turn until the needle is secure (Figure 6).

Do not over tighten as this may cause cracking of the needle hub resulting in leakage of the product during injection. The safety shield may also be damaged if the needle is screwed with too much force.

Should the needle hub crack, appear to be damaged, or have any leakage, the product should not be used. The damaged needle should not be substituted/replaced and the product should not be injected.
The entire product should be disposed of securely

In the event of damage to the needle hub, a new replacement product should be used.

Figure 6



Step 7
Move the safety shield away from the needle and pull off the protective needle cover immediately prior to administration (Figure 7).
**Important: Do not operate the safety needle mechanism before administration. Should the needle hub appear to be damaged, or leak, the product should NOT be used.
The damaged needle should NOT be replaced and the product should NOT be injected.
In the event of damage to the needle hub, use another ELIGARD kit.**

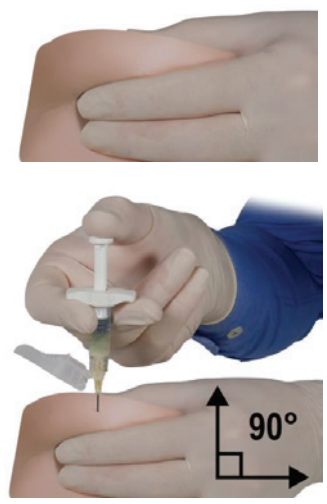
Figure 7

Step 8
Prior to administration, purge any large air bubbles from Syringe B. Administer the product subcutaneously whilst keeping the safety shield away from the needle.

Administration Procedure:

- Select an injection site on the abdomen, upper buttocks, or another location with adequate amounts of subcutaneous tissue that does not have excessive pigment, nodules, lesions, or hair and has not recently been used.
- Cleanse the injection-site area with an alcohol swab (not enclosed).
- Using the thumb and forefinger, grab and bunch the area of skin around the injection site.
- Using your dominant hand, insert the needle quickly at a 90° angle to the skin surface. The depth of penetration will depend on the amount and fullness of the subcutaneous tissue and the length of the needle. After the needle is inserted, release the skin.
- Inject the drug using a slow, steady push and press down on the plunger until the syringe is empty. Please ensure that the full amount of the product in Syringe B is injected before removing the needle.
- Withdraw the needle quickly at the same 90° angle used for insertion while maintaining pressure on the plunger.

Figure 8



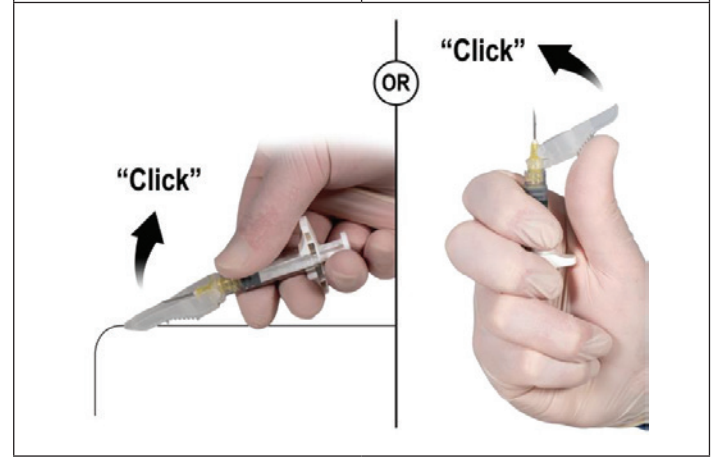
Step 9
After injection, lock the safety shield using any of the activation methods listed below.

1. Closure on a flat surface
Press the safety shield, lever side down, onto a flat surface (Figure 9a) to cover the needle and lock the shield.
Verify locked position through audible and tactile “click”.
Locked position will completely cover needle tip.

2. Closure with your thumb
Placing your thumb on the safety shield (Figure 9b), cover the needle tip and lock the shield.
Verify locked position through audible and tactile “click”.
Locked position will completely cover needle tip.

Figure 9a
Closure on a flat surface

Figure 9b
Closure with your thumb



Once safety shield is locked, immediately dispose of the needle and syringe in an approved sharps container.