1.3.2.1 Patient Information Leaflet

SCHEDULING STATUS

S4

ELIGARD ® 7,5 mg (injectable suspension)

ELIGARD ® 22,5 mg (injectable suspension)

ELIGARD ® 45 mg (injectable suspension)

Leuprolide acetate

Read all of this leaflet carefully before you are given ELIGARD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What ELIGARD is and what it is used for.
2. What you need to know before you are given ELIGARD.
3. How to use ELIGARD.
4. Possible side effects.
5. How to store ELIGARD.
6. Contents of the pack and other information.

1. What ELIGARD is and what it is used for

Leuprolide, the active medicine in ELIGARD, works by reducing the testosterone produced by the testicles.

Usually, prostate cancer shrinks or stops growing when the body's supply of testosterone is lowered. However, ELIGARD is not a cure for prostate cancer.

2. What you need to know before you receive ELIGARD

ELIGARD should not be administered:

- If you are hypersensitive (allergic) to the active ingredient leuprolide, or products that have a similar method of action, or any of the other ingredients of ELIGARD, listed in Section 6.
- In pregnancy and breastfeeding.
- If you are a woman or a child.
- 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 medicines for prostate cancer.

Warnings and precautions

Tell your healthcare provider before being given the injection:

- If you notice unusual bleeding, redness or pain at the injection site.
- In the first few weeks of treatment, if you experience increased pain throughout your body, weakness, or numbness.
- If you notice blood in your urine or have difficulty in passing water, contact your doctor immediately.
- Your doctor may measure blood levels of prostate-specific antigen (PSA) during your treatment with ELIGARD.
- If you have cardiovascular problems e.g. heart rhythm problems (dysrhythmia), you should consult your doctor as it may lead to a heart attack or stroke.
- If you suffer from irregular heartbeat which can result in fainting, dizziness, or sudden death or blood clots.

- If you have diabetes (elevated blood sugar levels).
- If you suffer from a type of lung disease that can cause scarring of lung tissue with symptoms such as shortness of breath, fever, and night sweats (see Section 4).
- ELIGARD may interfere with certain laboratory tests. Inform your healthcare professional if you are going for tests.
- If you suffer from a bad or recurrent headache, problems with your eyesight and ringing or buzzing in the ears contact your doctor immediately.

Severe skin rashes including Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (SJS/TEN) have been reported in association with leuprorelin. Stop using ELIGARD and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children/ and adolescents

ELIGARD was not studied in children and should not be used in children.

Other medicines and ELIGARD

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

Medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol).

Medicines that might increase the risk of heart rhythm problems (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Pregnancy and breastfeeding and fertility

ELIGARD is not intended for women.

You should not take ELIGARD if you are pregnant or breastfeeding your baby.
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ELIGARD.

Driving and using machinery

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, as ELIGARD **may affect** mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see 'Possible side- effects').
It is not always possible to predict to what extent ELIGARD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ELIGARD affects them.

3. How to receive ELIGARD

- ELIGARD will be injected under your skin.
- Your doctor will determine the correct dose for you.

The usual dose for ELIGARD is:

Dose	**7,5 mg**	**22,5 mg**	**45 mg**
Recom-mended dose	1 injection every month	1 injection every 3 months	1 injection every 6 months

- Your doctor will tell you how long your treatment with ELIGARD will last.
- If you have the impression that the effect of ELIGARD is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.
- You will not be expected to give yourself ELIGARD. It will be given to you by a person who is qualified to do so.

If you receive more ELIGARD than you should:

Since a healthcare professional will administer ELIGARD, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of ELIGARD:

Since a healthcare professional will administer ELIGARD, it is unlikely that the dose will be missed.

Effects when the treatment with ELIGARD is stopped:

- 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 healthcare professional.**

4. Possible side effects

ELIGARD can cause side effects.

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Not all side effects reported for ELIGARD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given ELIGARD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking ELIGARD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ELIGARD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A rare, but serious condition of bleeding into or impaired blood supply of the pituitary gland at the base of the brain (called pituitary apoplexy), may occur within the first 2 weeks of the first dose, and some within the first hour.
- Symptoms may include sudden headache, vomiting, changes of the eyes or vision, changes in your emotional status and sometimes serious effects on the heart (cardiovascular system).
- There may be some pain and discomfort during and after ELIGARD injection. Bruising and redness may occur. If they do not heal, contact your doctor.
- There is a chance that your bones may become thinner if you use ELIGARD for a long period of time.
- Skin eruption (pimples on the skin).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Hot flushes;
- fatigue;
- prostate cancer-related symptoms may become worse during the first few weeks of treatment;
- ELIGARD may cause impotence;
- skin reactions at the insertion site;
- and testicular atrophy;
- spontaneous bleeding in skin or mucous membrane, redness of the skin;
- nasopharyngitis (symptoms of common cold);
- nausea, malaise, diarrhoea, inflammation of the stomach and intestines (gastroenteritis/colitis);
- irregular trips to the toilet to pass water (also at night), difficulty in starting to pass water, painful urination, reduced urine output;
- rigors (episodes of exaggerated shaking with high fevers);
- prolonged bleeding time, changes in blood values, decreased red blood cells/low red blood cell count.

The following side effects have been reported less frequently:

- Sweating, sleeplessness, black-out, feeling of coldness, weakness, sleepiness;
- flatulence/winds, constipation, heartburn;
- weight gain;
- tremor, backache, joint pain, muscle weakness, limb pain;

- disturbance of smell and taste, depression, dizziness, convulsions;
- pain in testes, problems or inability to obtain an erection or to ejaculate, decreased libido, development of male breast tissue, breast soreness/ tenderness, decrease in size of testes, reduced penis size;
- hair loss, clamminess, night sweats, increased sweating;
- high blood pressure, low blood pressure;
- urinary tract infection;
- local skin infection;
- worsening of diabetes mellitus;
- abnormal dreams;
- abnormal involuntary movements;
- injection site necrosis.

The following side effects have been reported but the frequency is unknown:

- Scarring of lung tissue with symptoms such as shortness of breath, fever, and night sweats;
- 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);
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu- like symptoms (Stevens-Johnson syndrome/Toxic Epidermal Necrolysis);
- skin redness and itchy rash (Toxic skin eruption);

- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (Erythema Multiforme).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ELIGARD.

5. How to store ELIGARD

- Store in the original packaging material under refrigerated conditions (2 °C to 8 °C).
- Once outside the refrigerator this product may be stored in its original packaging at or below 25 °C for up to eight weeks prior to constitution.
- Do not remove from the outer carton until required for use.
- Keep all medicines out of the reach of children.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ELIGARD contains:

ELIGARD ® 7,5 mg:

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One prefilled syringe with powder for solution for injection contains 7,5 mg leuprorelin acetate, equivalent to 7,0 mg leuprorelin.

ELIGARD ® 22,5 mg:

One prefilled syringe with powder for solution for injection contains 22,5 mg leuprorelin acetate, equivalent to 21,0 mg leuprorelin.

ELIGARD ® 45 mg:

One prefilled syringe with powder for solution for injection contains 45 mg leuprorelin acetate, equivalent to 41,7 mg leuprorelin.

What ELIGARD looks like and contents of the pack:

Powder and solvent for solution for injection.

Powder (Syringe B):

Pre-filled syringe with a white to off-white powder.

Solvent (Syringe A):

Pre-filled syringe with a clear, colourless to pale yellow solution

A pre-connected syringe system consisting of:

- one pre-filled cyclic olefin copolymer syringe containing powder (Syringe B)
- one pre-filled polypropylene syringe containing solvent (Syringe A)
- a connector with latching button for Syringe A and B.

Syringe A has a plunger tip of thermoplastic rubber. The plunger tip of Syringe B is composed of chlorobutyl rubber.

The following pack sizes are available:

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- A kit consisting of a thermoformed tray and a 18-gauge or 20-gauge sterile needle in a cardboard carton. The tray contains one pre-connected syringe(s) system and a desiccant pouch.
- A bundle pack containing kits of 2 pre-connected syringe system

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website