



This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ELIGARD®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given ELIGARD?

ELIGARD contains the active ingredient leuporelin acetate. ELIGARD is used to reduce the symptoms of advanced cancer of the prostate gland, or to treat high-risk localised prostate cancer in combination with radiotherapy. ELIGARD is also used to treat early puberty in children 2 years of age and older (central precocious puberty).

For more information, see Section [1. Why am I being given ELIGARD?](#) in the full CMI.

2. What should I know before am I given ELIGARD?

Do not use ELIGARD if you have ever had an allergic reaction to leuporelin acetate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before am I given ELIGARD?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ELIGARD and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given ELIGARD?

- Your doctor will decide what dose of ELIGARD you will receive.
- ELIGARD should only be given to you by a doctor or nurse.

More instructions can be found in Section [4. How am I given ELIGARD?](#) in the full CMI.

5. What should I know while being given ELIGARD?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using ELIGARD.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop treatment with your medicine without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ELIGARD affects you.
Drinking alcohol	<ul style="list-style-type: none">• There is no information on the use of ELIGARD with alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep ELIGARD in a place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while being given ELIGARD?](#) in the full CMI.

6. Are there any side effects?

Swelling of face, lips, throat; chest pain; tingling/numbness in arms or legs; headache; vision problems; unconsciousness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using ELIGARD. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ELIGARD.**

Where to find information in this leaflet:

1. [Why am I being given ELIGARD?](#)
2. [What should I know before I am given ELIGARD?](#)
3. [What if I am taking other medicines?](#)
4. [How am I given ELIGARD?](#)
5. [What should I know about being given ELIGARD?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given ELIGARD?

ELIGARD contains the active ingredient leuporelin acetate.

In men, ELIGARD is used to reduce the symptoms of advanced cancer of the prostate gland, or to treat high-risk localised prostate cancer in combination with radiotherapy.

In children 2 years of age and older, ELIGARD is used to treat early puberty (central precocious puberty).

2. What should I know before am I given ELIGARD?

Warnings

ELIGARD should not be given if:

- you are allergic to leuporelin acetate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines (such as goserelin).
- you had surgical removal of your testes, as in that case ELIGARD does not lead to further decrease in serum testosterone levels
- you are pregnant or plan to become pregnant or are breastfeeding. If used during pregnancy, it may affect the developing baby.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have history of epilepsy, fits or seizures
- have tumour in your pituitary gland.
- have a history of mental (psychiatric) problems.

In Men

- have nerve problems caused by bone lesions in the spine, problems passing urine or blood in your urine. These conditions may get worse for a short time after treatment is started. Your doctor may prescribe another medicine when you first receive ELIGARD to reduce the likelihood of this occurring.
- have diabetes
- have cardiovascular disease, heart problems or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of you having further heart rhythm problems may increase with ELIGARD

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not be given this medicine if you are pregnant or plan to become pregnant or are breastfeeding.

This medicine has not been studied in women.

If used during pregnancy, it may affect the developing baby.

Fertility

Talk to your doctor about the effects ELIGARD may have on fertility.

This medicine may impair fertility in men. Use of this medicine for a short time has shown a full return to fertility after stopping the medicine. Fertility suppression may or may not be permanent when the medicine is given for a long time.

In Children

In the first few weeks after your child receives their first ELIGARD injection, ELIGARD can cause an increase in some hormones. During this time, you may notice more signs of puberty in your child including vaginal bleeding. Call your doctor straight away if signs of puberty continue after 2 months of receiving ELIGARD.

Some people given gonadotropin releasing hormone like ELIGARD have had new or worsened mental (psychiatric) problems. Call your doctor straight away if your child has any new or worsening emotional symptoms while taking ELIGARD.

Pseudotumor Cerebri/Idiopathic Intracranial Hypertension (in children)

A condition characterised by increased pressure inside the head has been reported in children receiving this medicine.

Monitor your child for symptoms, including headache, eye problems, including blurred vision, double vision and decreased eyesight, eye pain, ringing in the ears, dizziness and nausea. Contact your doctor immediately if your child has any of these symptoms during treatment with Eligard.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ELIGARD and affect how it works.

ELIGARD may interfere with some medicines used to treat heart rhythm problems, such as:

- quinidine
- disopyramide
- amiodarone
- sotalol.

ELIGARD may increase the risk of heart rhythm problems when used with other medicines which also have the same risk, such as:

- methadone (used for pain relief and part of drug addiction detoxification)
- moxifloxacin (an antibiotic)
- antipsychotics used for serious mental illness.

ELIGARD has not been found to interact with other commonly used medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ELIGARD.

4. How am I given ELIGARD?

How much to use

Your doctor will decide what dose of ELIGARD you will receive.

The recommended dose of ELIGARD for prostate cancer is one of:

- 7.5 mg injection every month or
- 22.5 mg injection every three months or
- 30 mg injection every four months or
- 45 mg injection every six months.

For central precocious puberty, the recommended dose is one 45mg injection every six months.

When am I given ELIGARD

- Continue treatment with your medicine for as long as your doctor tells you.

How am I given ELIGARD

- ELIGARD should only be given to you by a doctor or nurse.
- The content of the two syringes in the ELIGARD kit (one containing the active ingredient and the other containing the delivery system) will be mixed together, then injected underneath the skin. The site of the injection should be varied from time to time.

If you forget to use ELIGARD

If you have missed your injection, contact your doctor or pharmacist to find out what to do.

If you use too much ELIGARD (overdose)

As ELIGARD will be given to you under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you think that you or anyone else may have been given too much ELIGARD, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given ELIGARD?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some blood and other tests from time to time to make sure the medicine is working.

Call your doctor straight away if:

- your condition worsens
- you are about to be started on any new medicine.
- you are about to have any blood tests. It may interfere with the results of some tests.
- your child feels unwell (when being treated for central precocious puberty).

Remind any doctor or dentist or pharmacist you visit that you are using ELIGARD.

Things you should not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop treatment with your medicine without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ELIGARD affects you.

ELIGARD may cause fatigue, dizziness and visual disturbances in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- ELIGARD is usually stored in the refrigerator (below 8°C) in doctor's surgery or clinic, or at the pharmacy
- However, if ELIGARD is dispensed to you, keep it in a place where the temperature stays below 25°C. It may be stored in this manner for a period of up to 8 weeks prior to administration

Follow the instructions in the carton on how to care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Any ELIGARD which is not used will be disposed in a safe manner by your doctor.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Prostate cancer:</p> <ul style="list-style-type: none"> • short-lived burning, stinging, pain, redness or itching at the injection site • mild bruising at the injection site • fatigue • dizziness • feelings of warmth or periods of excessive sweating • pain or a decrease in size of the testicles • nausea, vomiting or diarrhoea • hair loss • more frequent urination • decreased libido • depression • changes in your breasts. <p>Central Precocious puberty:</p> <ul style="list-style-type: none"> • injection site pain • nasal congestion, sore throat, and runny nose (nasopharyngitis) • headache • cough • abdominal pain • nausea • constipation • vomiting • upper respiratory tract infection • sudden shortness of breath or wheezing (bronchospasm) • productive cough • fever (pyrexia) • sudden strong feelings of heat and sweating (hot flush). 	<p>Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
Prostate cancer: <ul style="list-style-type: none">• backache• tingling or numbness of the hands and feet• difficulty in passing urine• blood in your urine• bone pain or fractures (this may be a sign of weakening of the bones). Central Precocious puberty: <ul style="list-style-type: none">• vaginal irritation, bleeding or discharge• changes in mood, irritability, restlessness, aggression, anger• tearfulness, crying• seizures, fits or convulsions.• headache, eye problems, including blurred/double vision, and decreased eyesight, eye pain, ringing in the ears, dizziness and nausea.	Call your doctor, nurse or pharmacist straight away, you may require medical attention.

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin• headache and vomiting, eye problems, altered mental state, or collapse• chest pain.	Call your doctor, nurse or pharmacist immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription for injection by a doctor or nurse.

What ELIGARD contains

Active ingredient (main ingredient)	Leuporelin acetate
Other ingredients (inactive ingredients)	The Atrigel® delivery system consists of a biodegradable polymer, dissolved in a solvent (N-methyl-2-pyrrolidone). Each presentation of ELIGARD contains a different mixture and volume of the polymer.

Do not take this medicine if you are allergic to any of these ingredients.

What ELIGARD looks like

ELIGARD is available in a single use kit, containing a cardboard frame and two removable sealed plastic trays. The tray containing syringe A contains a syringe filled with the delivery system, known as the Atrigel® Delivery System, plus a long white replacement plunger rod and a desiccant pack (to absorb moisture). The tray containing syringe B contains a syringe filled with a powder which is the active ingredient, plus a needle and a desiccant pack (to absorb moisture).

Once the contents of syringe A and syringe B have been mixed together (prior to injection), the colour of the resulting liquid will be:

- light tan to tan for ELIGARD 1 month
- colourless to pale yellow for ELIGARD 3 month, ELIGARD 4 month and ELIGARD 6 month.

The mixed solution may appear slightly grey due to tiny air bubbles. This is acceptable and not representative of product quality.

ELIGARD comes in single packs.

ELIGARD comes in the following strengths:

ELIGARD 1 month 7.5 mg (AUST R 97449)

ELIGARD 3 month 22.5 mg (AUST R 97450)

ELIGARD 4 month 30 mg (AUST R 97451)

ELIGARD 6 month 45 mg (AUST R 101581)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Who distributes ELIGARD

Mundipharma Pty Limited

ABN 87 081 322 509

10 Carrington Street

SYDNEY NSW 2000

Phone: 1800 188 009

This leaflet was prepared in July 2022.

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ELIGARD CMI v1 (CCDS 17)