ELIGARD®

Leuprorelin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ELIGARD. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ELIGARD against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What Eligard® is used for

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. This medicine is similar to a hormone called gonadotrophin releasing hormone, which is normally released from the brain.

When it is given regularly to males, this medicine works by reducing the amount of testosterone produced. This inhibits the growth of prostate cancers which rely on testosterone to grow.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Eligard®

When you must not be given it

You must not be given ELIGARD if you have an allergy to:

- any medicine containing leuprorelin
- any of the ingredients listed at the end of this leaflet
- any other similar medicines, such as goserelin.

Some of the symptoms of an allergic reaction may include 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.

Do not use ELIGARD following surgical removal of your testes, as in that case ELIGARD does not lead to further decrease in serum testosterone levels.

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.

This medicine must not be given to children.

Safety and effectiveness in children have not been established.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you 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.

Tell your doctor if you have or ever had any of the following medical conditions:

- diabetes
- 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
- osteoporosis
- history of epilepsy, fits or seizures
- tumour in your pituitary gland.

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.

If you have not told your doctor about any of the above, tell him/her before you start treatment with ELIGARD.

Taking other medicines

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

ELIGARD may interfere with some medicines used to treat heart rhythm problems, such as:
• quinidine
• disopyramide
• amiodarone, and
• 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), and
• antipsychotics used for serious mental illness.

ELIGARD has not been found to interact with other commonly used medicines. Your doctor and pharmacist may have more information.

How Eligard® is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

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

The usual dose of ELIGARD is:

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

How it is given

ELIGARD should only be given to you by a doctor or nurse.
The contents 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.

How long it is given for

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

This medicine helps control your condition, but does not cure it. It is important that you continue to receive your medicine even if you feel well.

If you forget to have your injection

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

If you have too much (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, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

There have not been any unwanted effects seen with overdosage of ELIGARD.

While you are being given Eligard®

Things you must do

If your condition worsens, tell your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given ELIGARD.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.
If you are going to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.
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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how ELIGARD affects you.
This medicine may cause fatigue, dizziness and visual disturbances in some people. If you have these symptoms, take care when driving or operating machines.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given ELIGARD.

This medicine helps most people with prostate cancer, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

• 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.

The above list includes side effects which are usually mild.

Tell your doctor, nurse or pharmacist as soon as possible if you notice any of the following:
• backache
• tingling or numbness of the hands and feet
• difficulty in passing urine
• blood in your urine
• bone pain or fractures (these may be a sign of weakening of the bones).

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

• 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.

The above list includes very serious side effects.
You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.
Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After being given Eligard®

Storage

ELIGARD will be stored in the refrigerator (below 8°C) in the pharmacy.

Once 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.

Keep this medicine in the original pack until it is time to use it.
If you take it out of the pack, it may not keep well.

Do not store ELIGARD or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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 (7.5 mg leuprorelin acetate).
• colourless to pale yellow for ELIGARD® 3 Month (22.5 mg leuprorelin acetate), ELIGARD® 4 Month (30 mg leuprorelin acetate) and ELIGARD® 6 Month (45 mg leuprorelin acetate).

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.

Ingredients

ELIGARD® contains leuprorelin acetate as the active ingredient. 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.

ELIGARD® comes in the following strengths:

• ELIGARD® 1 Month
(7.5 mg leuprorelin acetate)
• ELIGARD® 3 Month
(22.5 mg leuprorelin acetate)
• ELIGARD® 4 Month
(30 mg leuprorelin acetate)
• ELIGARD® 6 Month
(45 mg leuprorelin acetate)

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

Sponsor

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AUST R numbers:
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• ELIGARD® 6 Month 101581