

LUCRIN INJECTION

leuprorelin acetate

CONSUMER MEDICINE INFORMATION

PLEASE READ THIS INFORMATION CAREFULLY

What is in this leaflet

This leaflet answers some common questions about Lucrin Injection.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Lucrin against the benefits they expect it will have on you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Lucrin is used for

Lucrin is a synthetic form of the naturally occurring gonadotropin releasing hormone.

This medicine is used to block the secretion of hormones from testes. In some types of cancer, these hormones help the cancer cells to grow. By blocking these hormones, Lucrin may slow or stop the growth of prostate cancer.

Lucrin should not be given to children.

Your doctor may have prescribed this medicine for another purpose. Ask your doctor if you have any questions about why Lucrin has been prescribed for you.

Lucrin is available only with a doctor's prescription.

Before you are given Lucrin

When you must not be given Lucrin

You must not be given Lucrin if you have ever had an allergy to other drugs similar to Lucrin or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You must not be given Lucrin if the packaging is broken or shows any signs of tampering.

You must not be given Lucrin if the use by date (Exp.) printed on the pack has passed.

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

Lucrin is not recommended for children.

Before you are given Lucrin

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have had any medical conditions, especially the following:

- if your cancer has spread to your spine
- difficulty or pain when passing urine
- history of convulsions, fits or seizures

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Lucrin.

Fertility:

Lucrin 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.

Children:

Lucrin has not been tested in children and so the safety and effectiveness in children is not known.

Taking other medicines

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

Lucrin has not been found to interact with other commonly used medicines. If you have any questions or concerns, discuss them with your doctor or pharmacist.

How Lucrin is given

Lucrin should only be given by your doctor or nurse.

Your doctor will tell you which formulation of Lucrin will be given and for how long. This may differ from the information contained in this leaflet.

How often Lucrin is given

Lucrin Injection

Recommended dose: 1 mg (0.2 mL) is injected daily under the skin.

Lucrin Depot 7.5 mg PDS Injection, Lucrin Depot 3- Month PDS and Lucrin Depot 4-Month PDS Injection should be mixed with the diluent before use according to the manufacturer's instructions provided.

Lucrin Depot 7.5 mg PDS Injection

Recommended dose: One Lucrin Depot 7.5mg PDS Injection is injected into a muscle once a month.

Lucrin Depot 3-Month PDS Injection

Recommended dose: One Lucrin Depot 3-Month PDS Injection is injected into a muscle every three months.

Lucrin Depot 4-Month PDS Injection

Recommended dose: One Lucrin Depot 4-Month PDS Injection is injected into a muscle every four months

The site of injection should be varied from time to time.

If you forget to have your injection

If you missed your injection, or are not sure what to do, check with your doctor or pharmacist.

Overdose

As Lucrin is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given this medicine, telephone your doctor immediately or the Poisons Information Centre (Australia:

Telephone 13 11 26; New Zealand: Telephone 0800 764 766) or go to Accident and Emergency at your nearest hospital.

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

While you are being given Lucrin

Things you must do

When Lucrin is first started, there may be a temporary increase in some hormones. This may cause an increase in pain or other symptoms of the cancer in the first weeks. If this happens see your doctor.

If symptoms include difficulty with urinating, a feeling of weakness or a numbness of the lower limbs, you should notify your doctor immediately.

These symptoms usually only happen with the first treatment with this medicine; you should not experience them with future treatments.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood tests from time to time to check on your progress.

Tell any other doctors, dentists and pharmacists who are treating you that you are being given Lucrin.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given this medicine.

If you do not feel well or your condition worsens, tell your doctor.

Things you must not do

Do not give this medicine to any one else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful driving or operating machinery until you know how Lucrin affects you.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

If Lucrin makes you feel dizzy or light-headed, be careful when getting up from a sitting or lying position. These are signs of low blood pressure.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

If you get any side effects, do not decide to stop using this medicine without first talking to your doctor.

Tell your doctor if you notice any of the following and they worry you:

- pain, swelling or redness at the injection site
- cough
- unusual tiredness or weakness
- tiredness sleepiness or drowsiness
- difficulty sleeping
- mild muscle, back or joint pain
- changes in testicular size
- change in your sexual drive
- inability to get or maintain an erection
- sweating and body odour
- hot flushes
- general pain

- nausea/vomiting
- buzzing, hissing, whistling, ringing or other persistent noise in the ears
- mild skin problems such as rash, itching, hives, dry skin or acne
- headache
- dizziness or light-headedness
- diarrhoea
- constipation

Tell your doctor as soon as possible if you notice any of the following:

- swelling in limbs
- problems with your eyesight
- difficulty breathing
- numbness or tingling of hands or feet
- blood in your urine
- difficulty or pain when passing urine
- changes in breast size

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

- swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing or sudden collapse
- unsteadiness when walking

These are very serious side effects. You may need urgent medical attention or hospitalisation. (These side effects are very rare).

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything that is making you feel unwell while you are given Lucrin or soon after you have finished your course of Lucrin even if it is not on this list.

Storage

Keep your medicine where children cannot reach them.

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines

Lucrin injection should be stored in a refrigerator (2°C-8°C). Do not freeze. Protect from light.

Lucrin Depot PDS Injections should be stored in a cool dry place where the room temperature stays below 25°C.

Disposal

If your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

- **MULTI-DOSE VIAL**

Description:

Lucrin 5 mg/mL Injection is a clear colourless liquid in a multidose glass vial.

Lucrin 5 mg/mL Injection may also be supplied as an injection kit, which consists of a multidose glass vial containing a clear colourless liquid, alcohol swabs and syringes with needles.

Ingredients:

Active ingredient:

leuprorelin acetate 5 mg/mL

Other ingredients:

sodium chloride, sodium hydroxide, acetic acid, water for injections.

Preservative:

benzyl alcohol

- **PREFILLED DUAL-CHAMBER SYRINGES**

Description:

Each Lucrin Depot 7.5 mg PDS Injection, Lucrin Depot - 3 Month

PDS Injection and Lucrin Depot - 4 Month PDS Injection contains:

1 dual-chamber syringe containing active ingredient (white powder) in the front chamber and diluent (colourless solution) in the rear chamber.

Ingredients

Lucrin Depot 7.5 mg PDS Injection:

Active ingredient: leuprorelin acetate 7.5 mg

Other ingredients: purified gelatine, mannitol and polyglactin.

Lucrin Depot 3-Month PDS Injection:

Active ingredient: leuprorelin acetate 22.5 mg

Other ingredients: polylactic acid, mannitol.

Lucrin Depot 4-Month PDS Injection:

Active ingredient: leuprorelin acetate 30 mg

Other ingredients: polylactic acid, mannitol.

The diluent contains:

carmellose sodium, mannitol, polysorbate 80 and water for injections.

Supplier

Abbott Australasia Pty Ltd
32 - 34 Lord Street
Botany NSW 2019
Australia

Australian registration numbers:

Lucrin 5 mg/mL Injection:
AUST R 29658

Lucrin Depot 7.5mg PDS Injection:
AUST R 114302

Lucrin Depot 3-Month PDS Injection:

AUST R 114303

Lucrin Depot 4-Month PDS

Injection:

AUST R 114304

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July 2010

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