

Lucrin® Injection

Leuprorelin acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lucrin Injection.

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 this medicine 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 Lucrin is used for

Lucrin is used to treat prostate cancer.

It belongs to a group of medicines called gonadotropin releasing hormone agonists.

It works by blocking 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.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Lucrin is available only with a doctor's prescription.

Lucrin should not be given to children.

Before you are given Lucrin

When you must not be given it

Do not receive Lucrin if you have an allergy to:

- any medicine similar to Lucrin
- any of the ingredients listed at the end of this leaflet

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Pregnancy and Breastfeeding

Although not relevant to prostate cancer patients, Lucrin should not be used during pregnancy or while breastfeeding.

Do not receive it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

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

Before are given Lucrin

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

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

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

- history of heart problems

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

Certain strengths of Lucrin have not been tested in children so the safety and effectiveness in children is not fully known.

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

Taking other medicines

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

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.

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

- medicines used to treat abnormal heart rhythms, e.g. quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide or ibutilide
- methadone, a medicine used to reduce withdrawal symptoms associated with drug addiction
- certain antibiotics such as moxifloxacin, a medicine used to treat infections caused by certain bacteria

- antipsychotic medicines

Taking these medicines together with Lucrin may increase the risk of abnormal heart rhythms.

How Lucrin is given

Lucrin should only be given by a 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 is 1mg (0.2mL) injected daily under the skin.

Lucrin Depot 7.5mg, 22.5mg, 30mg and 45mg PDS injection should be mixed with the diluent before use according to the manufacturer's instructions provided.

Lucrin Depot 7.5mg PDS is injected into a muscle once every 4 weeks.

Lucrin Depot 22.5mg PDS is injected into a muscle once every 12 weeks.

Lucrin Depot 30mg PDS is injected into a muscle once every 16 weeks.

Lucrin Depot 45mg PDS is injected into a muscle once every 24 weeks.

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

If the microspheres are not in suspension, the injection must not be administered.

How to take it

This medicine is given as an injection, usually into your muscle by a doctor or trained nurse with experienced in the administration of such injections.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

The medicine helps control your condition, but it does not cure it. It is important to keep taking your medicine even if you feel well.

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, or the Poisons Information Centre (telephone Australia 13 11 26), or go to Accident and Emergency at your nearest hospital.

There have not been any unwanted side 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 urinating, a feeling of weakness or numbness in 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.

Your doctor may continue to monitor your testosterone levels to ensure that acceptable suppression of the secretion of hormones from

the testes is maintained throughout your course of treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lucrin.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you are about 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.

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

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not use fractional doses or combinations of doses to substitute any depot formulations.

Due to different release characteristics of each presentation of Lucrin Depot, a fractional dose of the 3-month depot, 4-month depot or 6-month depot formulation is not equivalent to the same dose of the monthly formulation (Lucrin Depot 7.5 mg PDS) and should not be given. Similarly, fractional doses of the 30 mg or 45 mg formulations should not be used as a substitute for the 30 mg or 22.5 mg and multiples of the 7.5 mg presentation should not be used as a substitute for the 22.5 mg, 30 mg or 45 mg formulations.

Things to be careful of

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

It helps most people with prostate cancer, but it may have unwanted side effects in a few people. All medicines have some unwanted side effects. Sometimes they are serious, but 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 this list of possible side effects. You may not experience any of them.

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

Tell your doctor or pharmacist 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 ear
- mild skin problems such as rash, itching, hives, dry skin or acne
- headache
- dizziness or light-headedness
- diarrhoea
- constipation

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- swelling in limbs
- problems with your eyesight
- difficulty breathing
- thirst
- frequent passing of urine
- numbness or tingling of hands or feet
- blood in your urine
- difficulty or pain when passing urine
- changes in breast size
- chest pain
- feeling of weakness in arms(s) or leg(s)
- speech problems

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

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

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

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

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

Storage

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

Lucrin PDS Injections should be kept in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it 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 or pharmacist tells you to stop taking this medicine, or the 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.

PREFILLED DUAL- CHAMBER SYRINGES

Description:

Lucrin Depot 7.5 mg PDS Injection, Lucrin Depot - 3 Month PDS Injection, Lucrin Depot - 4 Month and Lucrin Depot - 6 Month PDS Injection is a dual-chamber syringe containing active ingredient (white powder) in the front chamber and diluent (colourless solution) in the rear chamber.

Ingredients

Lucrin multidose vial contains leuprorelin acetate 5 mg/mL as the active ingredient.

It also contains sodium chloride, sodium hydroxide, acetic acid, and water for injections.

It also contains the preservative: benzyl alcohol.

Lucrin Depot 7.5mg PDS contains 7.5mg leuprorelin acetate as the active ingredient.

It also contains gelatine, mannitol and polyglactin.

Lucrin Depot 22.5mg PDS contains 22mg leuprorelin acetate as the active ingredient.

It also contains polylactic acid and mannitol.

Lucrin Depot 30mg PDS contains 30mg leuprorelin acetate as the active ingredient.

It also contains polylactic acid and mannitol.

The diluent contains carmellose sodium, mannitol, polysorbate 80 and water for injections.

Lucrin Depot 45mg PDS contains 45mg leuprorelin acetate as the active ingredient.

It also contains polylactic acid, stearic acid and mannitol.

The diluent contains carmellose sodium, mannitol, polysorbate 80, glacial acetic acid and water for injections.

Supplier

Lucrin multidose vial is made in France.

Lucrin Depot PDS is made in Japan.

Lucrin is supplied in Australia by:

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
1800 043 460
ABN: 48 156384262

This leaflet was prepared in May 2015.

Australian Registration Number(s)

Lucrin 5 mg/mL Injection: AUST R 29658

Lucrin Depot 7.5mg 1 Month PDS Injection: AUST R 114302

Lucrin Depot 22.5mg 3-Month PDS Injection: AUST R 114303

Lucrin Depot 30mg 4-Month PDS Injection: AUST R 114304

Lucrin Depot 45mg 6-Month PDS Injection: AUST R 222375

Version 11