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 using Lucrin?

Lucrin contains the active ingredient leuprorelin acetate. Lucrin is used to treat prostate cancer in men and precocious (unusually early) puberty in children.

For more information, see Section 1. Why am I using Lucrin? in the full CMI.

2. What should I know before I use Lucrin?

Check the list of ingredients at the end of the CMI. Do not use Lucrin if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that 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 I use Lucrin? in the full CMI.

3. What if I am using other medicines?

Some medicines may interfere with Lucrin and affect how it works or Lucrin may interfere with other medicines and affect how they work.

A list of these medicines is in Section 3. What if I am using other medicines? in the full CMI.

4. How do I use Lucrin?

- Lucrin Injection is given by your doctor or nurse.
- The Lucrin dose and how frequently it is given is based on your doctor's assessment.

More instructions can be found in Section 4. How do I use Lucrin? in the full CMI.

5. What should I know while using Lucrin?

Things you should do	 Keep all your appointments, including those for blood tests or bone density checks. Remind any doctor or dentist you visit that you are using Lucrin.
Things you should not do	Do not miss a scheduled injection.
Driving or using machines	It is unlikely that Lucrin will affect your ability to drive or use machines.
Drinking alcohol	There is no information on the use of Lucrin with alcohol.
Looking after your medicine	Store Lucrin in a cool dry place away from sunlight.

For more information, see Section 5. What should I know while using Lucrin? 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.

Active ingredient: leuprorelin acetate(loop-ror-el-lin ass-set-tayt)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lucrin. 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 it.

Where to find information in this leaflet:

- 1. Why am I using Lucrin?
- 2. What should I know before I use Lucrin?
- 3. What if I am taking other medicines?
- 4. How do I use Lucrin?
- 5. What should I know while using Lucrin?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Lucrin?

Lucrin contains the active ingredient leuprorelin acetate.

Lucrin is used to treat prostate cancer in men, and unusually early puberty in children (central precocious puberty).

2. What should I know before I use Lucrin?

Warnings

Do not use Lucrin if:

- 1. you are allergic to leuprorelin acetate, or any of the ingredients listed at the end of this CMI.
- 2. you are pregnant or breastfeeding, although unlikely unless your doctor has prescribed Lucrin for another condition.

Check with your doctor if:

- you have or have had convulsions or seizures
- you have diabetes
- you have had a heart attack or stroke
- you have high blood pressure or cholesterol
- you have or have had depression (low mood, anxiety, feeling of worthlessness)
- your cancer has spread to the spine (when being treated for prostate cancer)
- you have any other medical conditions not already discussed with your doctor
- you take any medicines for any other condition.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Although not expected to be applicable, make sure your doctor is aware you are pregnant or are breastfeeding.

Hormonal Flare

Symptoms may increase at the beginning of treatment. This is applicable to patients being treated for prostate cancer (also known as tumour flare) and precocious puberty. Refer to **Section 6 Are there any side effects?** for advice on

symptoms of hormonal flare and what to do if you experience any of them.

Pituitary apoplexy (in children)

The pituitary gland is a small gland in your brain that plays a major role in regulating body functions and general wellbeing. Pituitary apoplexy is a condition where blood flow is restricted into the pituitary gland. If your child experiences symptoms including sudden headache, vomiting, changes to vision, unconsciousness, then urgent medical attention is required.

Pseudotumor cerebri (PTC)/idiopathic intracranial hypertension

A condition characterised by increased pressure inside the head (intracranial pressure) for no obvious reasons has been reported in children receiving this medicine.

Monitor/watch your child for signs and symptoms of PTC including headache, vision issues such as blurred vision, double vision, loss of vision, pain behind the eye or pain with eye movement, ringing in the ears, dizziness, and nausea. Contact your doctor immediately and take your child to an ophthalmologist (an eye specialist) to find out if there is papilloedema (pressure in or around the brain which causes the part of the optic nerve inside the eye to swell). If papilloedema is present, this means your child has PTC and immediate treatment is necessary.

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 Lucrin and affect how it works, while Lucrin may affect how other medicines work.

Medicines that may <u>increase</u> the risk of developing irregular heart rhythms:

- quinidine, a medicine used to treat certain heart conditions
- disopyramide, a medicine used to treat marked changes in heart rhythms
- procainamide, a medicine used to treat changes in heart rate, whether fast slow or irregular
- amiodarone, a medicine used to treat marked changes in heart rhythm
- sotalol, a medicine used to treat certain heart conditions
- dofetilide and ibutilide, medicines used to maintain normal heart rhythm
- methadone, a medicine used to treat strong pain and to help with addiction to drugs like heroin
- certain medicines used to treat infections caused by bacteria, antibiotics, e.g.moxifloxacin
- medicines used to treat certain mental and emotional conditions (e.g. risperidone, olanzapine, clozapine).

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

4. How do I use Lucrin?

How much to use

- The Lucrin dose and how often it is to be injected is determined by your doctor
- Lucrin is given as an injection into the muscle by your doctor or nurse.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Lucrin.

If you use too much Lucrin

As Lucrin is injected by your doctor or nurse, it is unlikely that you will receive too much. If you have any concerns about having received too much Lucrin, medical attention may be required.

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 using Lucrin?

Things you should do

- Keep all doctor's appointments to ensure you receive Lucrin regularly and your progress can be checked
- Keep all blood test appointments to keep track of progress and to monitor for side effects.

Call your doctor straight away if:

- you notice an increase in symptoms
- you experience an increase in pain, difficulty passing urine, feeling weak or numb in your legs (when being treated for prostate cancer)
- your child feels unwell (when being treated for precocious puberty).

Remind any doctor or dentist you visit that you are using Lucrin.

Things you should not do

• Do not miss a scheduled injection.

Driving or using machines

It is unlikely that Lucrin will affect your ability to drive or use machines.

Looking after your medicine

Follow the instructions on the carton on how to take 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
- do not store it in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

Le	ss serious side effects	What to do
Pro	ostate cancer: pain, swelling or redness at the injection site cough unusual tiredness or weakness, feeling drowsy dizziness or light-headedness	Speak to your doctor if you have any of these less serious side effects and they worry you.
• • • • • • • •	difficulty sleeping headache mild muscle, back or joint pain changes in testicular size change in sex drive or inability to get or maintain an erection hot flushes, sweating, body odour nausea/vomiting diarrhoea constipation ringing in the ear rash, itching, hives, dry skin or acne	
Pre	ecocious puberty:	
• • • • • • • • • • • • • • • • • • • •	pain, swelling, redness at the injection site general pain hot flushes, sweating dizziness, light-headedness rash, itching, hives, dry skin, acne vaginal irritation, bleeding or discharge increased weight changes in mood, irritability, restlessness, aggression tearfulness, crying	

Serious side effects

urine

Serious side effects	What to do
 Prostate cancer: swelling in arms or legs changes to breasts problems with vision difficulty breathing thirst frequent passing of urine difficulty or pain when passing 	Call your doctor straight away, if you notice any of these serious side effects.

Serious side effects	What to do
 blood in the urine numbness or tingling of hands or feet chest pain problems with speech. 	
Precocious puberty:	
 swelling in arms or legs bone loss (decreased bone mineral density) problems with your vision difficulty breathing numbness or tingling of hands or feet changes in breast size blood in the urine headache, blurred/double or loss of vision, pain behind the eye or with eye movement, ringing in the ears, dizziness, nausea. 	

Very serious side effects

Very serious side effects	What to do
 Prostate cancer: swelling of the face, lips, mouth, throat which may cause difficulty in swallowing or breathing feeling of weakness in arms or legs unsteadiness when walking chest pain sudden collapse. Precocious puberty: swelling of the face, lips, mouth, throat which may cause difficulty in swallowing or breathing unsteadiness when walking sudden headache vomiting changes to vision unconsciousness. 	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 <u>www.tga.gov.au/</u> <u>reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What Lucrin contains

Lucrin 1-month 7.5 mg Depot Injection

Active ingredient

Leuprorelin acetate

(main ingredient)	
Other ingredients	polyglactin
(inactive	mannitol
ingredients)	 carmellose sodium
ing calonic,	gelatin
	 polysorbate 80
	glacial acetic acid
	 water for injections

Lucrin 3-month 22.5 mg Depot Injection Lucrin 4-month 30 mg Depot Injection Lucrin Paediatric 30 mg Depot Injection

Active ingredient (main ingredient)	Leuprorelin acetate
Other ingredients (inactive ingredients)	 polylactic acid mannitol carmellose sodium polysorbate 80 glacial acetic acid water for injections

Lucrin 6-Month 45 mg Depot Injection

Active ingredient (main ingredient)	Leuprorelin acetate
Other ingredients (inactive ingredients)	 polylactic acid mannitol stearic acid carmellose sodium polysorbate 80 glacial acetic acid water for injections

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

What Lucrin looks like

Lucrin is available in prefilled dual chamber syringes containing white powder in the front chamber and liquid in the rear chamber. Before injecting, the liquid is pushed into the front chamber to be mixed with the powder.

Lucrin 1-month 7.5 mg Depot Injection (AUST R 114302)

Lucrin 3-month 22.5 mg Depot Injection (AUST R 114303)

Lucrin 4-month 30 mg Depot Injection (AUST R 114304)

Lucrin 6-month 45 mg Depot Injection (AUST R 222375)

Lucrin Paediatric 30 mg Depot Injection (AUST R 218936).

Who distributes Lucrin?

Lucrin is distributed in Australia by: AbbVie Pty Ltd

ABN 48 156 384 262

241 O'Riordan Street

Mascot NSW 2020

This leaflet was prepared on 1 July 2021.