

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; uterine fibroids, endometriosis and breast cancer in women; 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 have 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 taking 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 taking 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 Monitor your blood glucose regularly if you have diabetes Remind any doctor, nurse, dentist or pharmacist 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 but take care until you know how it affects you.	
Drinking alcohol	There is no information on the effects of taking 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?

Very serious side effects include swelling of the face, lips or throat; pain in your chest or arms that may spread to your neck, jaw or back; tingling/numbness in your arms or legs; intense pain, redness, or heat in the leg; headache; vision problems; and 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(s): [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 Lucrin.

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:

- in men, to treat prostate cancer,
- in women, to treat uterine fibroids (growths in the uterus or womb that are not cancer),
- in women, to treat endometriosis (where cells from the lining of the uterus are found outside of the uterus),
- in women, to treat breast cancer where treatment with hormones has not worked, and
- in children, to treat precocious puberty (unusually early puberty).

2. What should I know before I use Lucrin?

Warnings

Do not use Lucrin if:

- you are allergic to leuprorelin acetate or a similar medicine, or any of the ingredients listed at the end of this leaflet
- you are pregnant or breastfeeding
- you have vaginal bleeding that you have not discussed with your doctor.

Check with your doctor if you:

- you have or have had convulsions or seizures
- you have or have had a brain injury or brain tumour
- you have diabetes
- you have had a heart attack or stroke
- you have or have had deep vein thrombosis (DVT, where a blood clot forms in a vein located deep inside your body, often in your leg)
- you have high blood pressure or cholesterol
- have or have had problems with your heartbeat (fast, slow or irregular)

- you have osteoporosis (reduced density and strength of the bones)
- your cancer has spread to the spine (if you are being treated for prostate cancer)
- you have used a similar medicine within the past six months
- you have any other medical conditions not already discussed with your doctor
- 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 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, think you might be pregnant or plan to become pregnant, or are breastfeeding or intend to breastfeed.

At the start of treatment

Your symptoms may increase at the beginning of treatment. They will usually start to improve in around 2 to 4 weeks. Speak to your doctor if you notice an increase in your symptoms.

Allergic Skin Reactions

Very rare, severe allergic skin reactions that include a rash with blisters and peeling called Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis have been reported. If you develop these symptoms after receiving Lucrin, contact your healthcare provider right away or get emergency medical help.

Pseudotumor cerebri (PTC)/idiopathic intracranial hypertension (in children)

A condition characterised by increased pressure inside the head (intracranial pressure) for no obvious reason 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.

Metabolic syndrome (in men)

If you are male and have a history of high blood sugar, diabetes, high cholesterol and/or fatty liver, your doctor should monitor you closely.

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 seizures or fits include:

- Bupropion, used for depression and to support smoking cessation
- a type of medicine used to treat depression, including fluoxetine, paroxetine, sertraline.

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

- quinidine, used to treat certain heart conditions
- disopyramide, used to treat marked changes in heart rhythms
- amiodarone, sotalol, used to treat certain heart conditions
- dofetilide, ibutilide, used to maintain normal heart rhythm
- methadone, used to treat strong pain and to help with addiction to drugs like heroin
- moxifloxacin, used to treat infections caused by bacteria (antibiotic)
- medicines used to treat certain mental and emotional conditions.

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

- Your doctor will determine the correct dose and how often it is to be injected, depending on your needs.
- Lucrin is mixed and injected by your doctor or nurse according to the instructions provided in the carton.

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, you may need medical attention.

You should immediately:

- phone the National Poisons Centre on 0800 POISON (0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appears to be no signs of discomfort or poisoning.

5. What should I know while using Lucrin?

Things you should do

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

Call your doctor straight away if:

- you notice an increase in your symptoms
- you/your child experience(s) a seizure or fit
- you experience an increase in pain, difficulty passing urine, feeling weak or numb in your legs (when being treated for prostate cancer)
- you become pregnant while receiving Lucrin
- you experience heavy bleeding (like a very heavy period)
- your child feels unwell (when being treated for precocious puberty).

Remind any doctor, nurse, dentist or pharmacist 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, but do not drive if you feel dizzy or lightheaded.

Drinking alcohol

There is no information on the effects of using Lucrin with alcohol.

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 a windowsill
- Store Lucrin below 25°C
- Keep the injection in the carton to protect it from light
- Once the powder and liquid have been mixed, the injection must be used within 24 hours.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

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

Les	Less serious side effects What to do	
•	pain, redness, itching or swelling at the site of the injection.	Speak to your doctor if you have any of these less
Prostate cancer:		serious side
•	buildup of fluid	effects and
•	feeling sick or dizzy	they worry you.
•	vomiting	
•	hot flushes, increased sweating	
•	feeling very tired, lacking energy	
•	muscular weakness	
•	changes in weight	
•	loss of appetite	
•	changes in mood, feelings of worthlessness	
•	headache	
•	dizziness or lightheadedness	
•	constipation or diarrhoea	
•	changes in sex drive, erectile	
	dysfunction	
•	reduced testicle size, testicular	
	pain	
•	waking through the night to pass	
	urine	
•	swelling and tenderness of the	
	breasts	
	trouble sleeping skin changes, dryness, rash,	
	itching, abnormal pigmentation	
•	prostate pain	
•	increased or abnormal hair	
	growth.	
Fih	roids, endometriosis and breast	
	ncer:	
•	sore throat and/or nose	
•	cough	
•	buildup of fluid in body	
•	feeling sick or dizzy	
•	vomiting	
•	hot flushes, increased sweating	
•	feeling very tired or drowsy,	
	lacking energy	
•	changes in mood, feelings of	
	worthlessness	
•	headache	
•	dizziness or lightheadedness	

Less serious side effects What to do		What to do
•	feeling unusually nervous or	
	anxious	
•	feeling agitated, irritated or	
	hostile	
•	changes in appetite	
•	changes in weight	
•	changes in sex drive	
•	unusual changes in mood	
•	difficulty sleeping	
•	swelling and tenderness of the	
	breasts	
•	changes in breast size	
•	skin changes, redness, dryness,	
	rash, itching, bumps,	
	pigmentation	
•	changes in nails	
•	pain and inflammation of the	
	vagina, discharge	
•	painful periods	
•	pelvic pain	
•	painful sexual intercourse	
•	increased or abnormal hair	
	growth	
•	being unusually active	
•	indigestion or excessive wind	
•	sore mouth, mouth ulcer(s) or	
	inflamed gums	
•	dry mouth	
•	muscle twitches	
•	waking through the night to pass	
	urine	
•	frequent urination	
•	feeling thirsty	
•	bleeding at the injection site.	
Pre	cocious puberty:	
•	changes in mood	
•	headache	
•	hot flushes	
•	skin changes, rash, redness, acne	
•	in girls: pain and inflammation of	
	the vagina, discharge	
•	swelling of the breasts	
•	increased weight.	

Serious side effects

Serious side effects	What to do
 Prostate cancer: bone pain, pain in back or joints. burning on passing urine swelling of the penis shortness of breath or difficulty breathing swelling of parts of your body 	Call your doctor straight away, if you notice any of these serious side effects.

Ser	ious side effects	What to do
•	tingling or numbness of the hands or feet.	
Fib	roids, endometriosis, and breast	
car	icer:	
•	burning on passing urine	
•	swelling in the neck	
•	heavy vaginal bleeding	
•	breast pain or tenderness or	
	other breast changes, including	
	secretion of breast milk	
•	back or joint pain	
•	bone pain	
•	unusual muscle stiffness or pain,	
	including neck	
•	feeling very depressed	
•	feeling confused or having	
	abnormal thoughts loss of	
	memory	
•	decreased feeling or sensitivity	
	on the skin	
•	fainting	
	migraine	
	shaking, tremors or abnormal coordination	
	conjunctivitis, itching of the eyes	
•	deafness, ringing or swelling in	
	the ears	
•	fast or irregular heartbeat	
•	nose bleeds	
•	shortness of breath or difficulty	
	breathing	
•	a swollen or sore stomach	
•	fever or chills	
•	change to liver (inflamed or	
	increase in fat buildup).	
Precocious puberty:		
•	noticeable changes in mood,	
	such as crying, feeling irritated,	
	angry or acting aggressive	
•	hearing voices or see things that	
	are not really there	
•	headache, blurred/double or	
	loss of vision, pain behind the	
	eye or with eye movement,	
	ringing in the ears, dizziness,	
	nausea.	
•	vaginal bleeding.	

Very serious side effects

cry serious side effects		
Very serious side effects	What to do	
 All uses: allergic skin reactions that may include a rash with blisters and peeling swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing. Prostate cancer: 	Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.	
 swelling or redness along a vein, which is extremely tender when touched feeling of weakness in arms or legs unsteadiness when walking difficulty passing urine blood in the urine. 		
Fibroids, endometriosis, and breast cancer:		
 intense pain, redness, or heat in the leg tingling/numbness in arms or legs weakness or numbness difficulty speaking dizziness, loss of balance convulsions vision problems vomiting blood or blood in stools difficulty passing urine sudden, severe headache unsteadiness when walking pain in chest or arms that may spread to your neck, jaw or back. 		

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 any side effects to https://pophealth.my.site.com/carmreportnz/s/. 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 Lucrin contains

Lucrin Depot 3.75 mg injection

Active ingredient (main ingredient)	leuprorelin acetate
Other ingredients (inactive ingredients)	 glacial acetic acid carmellose sodium gelatin PLGA (copoly (dl-lactic acid/glycolic acid) mannitol Polysorbate 80 Water for injection

Lucrin Depot 11.25 mg injection

Active ingredient	leuprorelin acetate
(main ingredient)	
Other ingredients (inactive ingredients)	 glacial acetic acid carmellose sodium polylactic acid mannitol Polysorbate 80 Water for injection

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, your doctor or nurse will mix the liquid with the powder in the syringe.

(Not all presentations may be available in New Zealand)

Who distributes Lucrin?

Lucrin is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand

Phone: 0800 900 030

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This leaflet was prepared in October 2023.

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