LUCRIN® DEPOT PDS

A prefilled dual-chambered syringe (PDS) for injection containing 3.75 mg and 11.25 mg of leuprorelin acetate

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you are given LUCRIN DEPOT PDS.

This leaflet answers some common questions about LUCRIN DEPOT PDS.

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 DEPOT PDS 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 DEPOT PDS is used for

LUCRIN DEPOT PDS is a synthetic form of the naturally occurring gonadotropin releasing hormone.
LUCRIN DEPOT PDS is used to block the secretion of hormones and can be used in the following conditions:

Prostate Cancer (3.75mg and 11.25mg)
Endometriosis, Uterine Fibroids and Breast Cancer (3.75mg and 11.25mg)
Central Precocious Puberty (early onset of puberty) in children (3.75mg)

Your doctor may have prescribed LUCRIN DEPOT PDS for another purpose. Ask your doctor if you have any questions about why LUCRIN DEPOT PDS has been prescribed for you.

LUCRIN DEPOT PDS is available only with a doctor's prescription.

LUCRIN DEPOT PDS is not addictive.

Before you are given LUCRIN DEPOT PDS

When you must not be given LUCRIN DEPOT PDS

You must not be given LUCRIN DEPOT PDS if you have ever had an allergy to other drugs similar to LUCRIN DEPOT PDS 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 DEPOT PDS if the packaging is broken or shows any signs of tampering.

You must not be given LUCRIN DEPOT PDS 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.

Bone Density: LUCRIN DEPOT PDS reduces the level of hormones required to maintain bone strength. This increases the risk of a reduction in bone density. This effect may only be partly reversed after therapy is stopped.

Particular care should be taken if you:

- Have a family history of osteoporosis
- Are of slight build
- Are a heavy smoker
- Have a low calcium intake
- Have menstrual disturbances
- Are immobile

- Are taking corticosteroid medication

The risk of developing osteoporosis should be discussed with your doctor.

Convulsions: Convulsions have been reported in patients on LUCRIN therapy. Tell your doctor if you have a history of convulsions, fits or seizures.

Pregnancy: LUCRIN DEPOT PDS should not be used in women who are pregnant. A barrier method of contraception should be used during treatment if required.

Lactation: LUCRIN DEPOT PDS should not be used while breast feeding.

You must not be given LUCRIN DEPOT PDS if you have undiagnosed vaginal bleeding.

Before you are given LUCRIN DEPOT PDS

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
- any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using LUCRIN DEPOT PDS.

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

Fertility: LUCRIN DEPOT PDS may impair fertility in men. Use of LUCRIN DEPOT PDS 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.

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 DEPOT PDS might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone used for pain relief and part of drug addiction detoxification, moxifloxacin - an antibiotic, and antipsychotics used for serious mental illness).

Other than what has been mentioned above, LUCRIN DEPOT PDS 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 DEPOT PDS is given

LUCRIN DEPOT PDS should only be given by your doctor or nurse.

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

How often LUCRIN DEPOT PDS is given

LUCRIN DEPOT PDS 1-Month 3.75 mg Injection and LUCRIN DEPOT PDS 3-Month 11.25 mg Injection should be mixed with the diluent before use according to the manufacturer's instructions provided.

LUCRIN DEPOT PDS 1-Month 3.75 mg Injection
Recommended dose: For prostate cancer, endometriosis, uterine fibroids and breast cancer, One LUCRIN DEPOT PDS 1-Month 3.75mg Injection is injected once **a month.**

For endometriosis and uterine fibroids, treatment should not exceed 6 months.
For central precocious puberty, the dose must be individualised for each child based on a ratio of medicine to body weight.

LUCRIN DEPOT PDS 3-Month 11.25 mg Injection
Recommended dose: One LUCRIN DEPOT PDS 3-Month 11.25 mg Injection is injected **every three 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 DEPOT PDS 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 LUCRIN DEPOT PDS, tell your doctor immediately or telephone the National Poisons Centre on 0800 POISON or 0800 764 766 for advice, or go to Accident and Emergency at your nearest hospital.

There have not been any unwanted effects seen with the overdosage of LUCRIN DEPOT PDS.

While you are being given LUCRIN DEPOT PDS

Things you must do

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

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

These symptoms usually only happen with the first treatment with LUCRIN DEPOT PDS; 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 DEPOT PDS.

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

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

Things you must not do

Do not give this medicine to anyone 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 DEPOT PDS affects you.

Make sure you know how you react to LUCRIN DEPOT PDS 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 DEPOT PDS 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.

In some children, bone loss (decreased bone mineral density) may occur during the treatment of central precocious puberty with LUCRIN DEPOT PDS. However, after the treatment is stopped, bone loss is reversed and may come back to normal levels in late adolescence.

Side Effects

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

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 LUCRIN DEPOT PDS 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
- Dryness of the vagina
- Breast changes
- Insomnia
- Mood swings
- Nervousness
- Change in weight
- Joint disorder
- Decreased libido
- Depression
- Shortness of breath
- feeling of warmth
- common cold syndrome
- dermatitis
- fever
- change in physical ability
- change in appetite
- hair loss
- cervical pain
- discharge and itching in the vagina

Some children taking LUCRIN DEPOT PDS have had new or worsened mental (psychiatric) problems. Mental (psychiatric) problems may include emotional symptoms such as:

- crying
- irritability
- restlessness (impatience)
- anger
- acting aggressive

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 DEPOT PDS or soon after you have finished your course of LUCRIN DEPOT PDS even if it is not on this list.

After using LUCRIN DEPOT PDS

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 DEPOT PDS injection should be stored in a cool dry place where the room temperature stays below 25ºC.

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

Each LUCRIN DEPOT PDS 1-Month (3.75 mg) and 3-month (11.25 mg) Injection kit 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 PDS 1-Month 3.75 mg Injection:
Active ingredient:
leuprorelin acetate 3.75 mg
Other ingredients:
gelatine, mannitol, PLGA (Copoly (DL-lactic acid/glycolic acid)).

LUCRIN DEPOT PDS 3-Month 11.25 mg Injection:
Active ingredient:
leuprorelin acetate 11.25 mg
Other ingredients:
polylactic acid, mannitol.

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

Sponsor

LUCRIN DEPOT PDS is distributed by:

AbbVie Limited
6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand

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