Patient Information Leaflet

SCHEDULING STATUS

S4

LUCRIN DEPOT 11,25 mg PDS Lyophilised microspheres and sterile diluent for suspension for injection

leuprolide acetate

Contains mannitol

Read all of this leaflet carefully before you are given LUCRIN DEPOT 11,25 mg PDS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LUCRIN DEPOT 11,25 mg PDS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1 What LUCRIN DEPOT 11,25 mg PDS is and what it is used for

LUCRIN DEPOT 11,25 mg PDS is a GnRH agonist, which inhibits gonadotropin (a hormone) secretion. LUCRIN DEPOT 11,25 mg PDS is used in men to treat prostate cancer, in women for the treatment of endometriosis, uterine fibroids and breast cancer.

2 What you need to know before you use LUCRIN DEPOT 11,25 mg PDS

LUCRIN DEPOT 11,25 mg PDS should not be administered to you:

- If you are hypersensitive (allergic) to GnRH, GnRH agonist analogues or any of the other ingredients (see section 6).
- If you have undiagnosed, abnormal vaginal bleeding.
- If you are or may become pregnant while receiving LUCRIN DEPOT 11,25 mg PDS.
- If you are breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you engage in sexual intercourse. Although LUCRIN DEPOT 11,25 mg PDS causes periods to stop, it is not a contraceptive. You should use non-hormonal contraceptives (i.e. barrier methods), while you are taking LUCRIN DEPOT 11,25 mg PDS.
- During the first weeks of treatment. You may experience an increase in clinical signs and symptoms during the initial days of therapy.

- If you have a history of or risk factors for QT prolongation or are receiving any medication that might prolong the QT interval. Please consult your doctor.

In men

- If you have a history of high blood sugar, diabetes, and/or high cholesterol, your doctor should monitor you closely for metabolic syndrome/changes.

Other medicines and LUCRIN DEPOT 11,25 mg PDS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Interactions with other medicines are not expected to occur.

Pregnancy, breastfeeding and fertility

The safe use of LUCRIN DEPOT 11,25 mg PDS in pregnancy has not been established. It is not known if LUCRIN DEPOT 11,25 mg PDS is excreted in human breast milk. Therefore, if you are pregnant or breastfeeding, think you may be pregnant, or planning to have a baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Driving and using machines

Take special care when you drive or operate machinery as LUCRIN DEPOT 11,25 mg PDS may make you feel drowsy. It is not always possible to predict to what extent LUCRIN DEPOT 11,25 mg PDS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LUCRIN DEPOT 11,25 mg PDS affects them.

3 How to use LUCRIN DEPOT 11,25 mg PDS

Do not share medicines prescribed for you with any other person.

The recommended dose is 11,25 mg given every 3 months as an intramuscular injection or injection under your skin.

You will not be expected to give yourself LUCRIN DEPOT 11,25 mg PDS. It will be given to you by a person who is qualified to do so.

If you are administered more LUCRIN DEPOT 11,25 mg PDS than you should receive

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you stop using LUCRIN DEPOT 11,25 mg PDS

Upon withdrawal of therapy and after LUCRIN DEPOT 11,25 mg PDS has cleared your system, you should notice full reversibility of hormone suppression.

4 Possible side effects

LUCRIN DEPOT 11,25 mg PDS can have side effects.

Not all side effects reported for LUCRIN DEPOT 11,25 mg PDS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LUCRIN DEPOT 11,25 mg PDS, please consult your health care professional for advice.

If you notice any of the following after taking LUCRIN DEPOT 11,25 mg PDS, stop taking LUCRIN DEPOT 11,25 mg PDS and tell your doctor immediately or go to the nearest hospital:

- Swelling of hands, feet, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Changes in the way your heart beats;
- Chest pain;
- Shortness of breath;
- Numbness in arms and legs;
- Unexpected or unusual heavy bleeding;
- Extreme weakness;
- Fainting;
- Yellowing of the skin and eyes.

These are all serious side effects. You may need immediate medical attention.

Tell your doctor as soon as possible if you notice any of the following after taking LUCRIN DEPOT 11,25 mg PDS:

- Mental impairment including thoughts of suicide or depression;
- Nausea;
- Headaches;
- Dizziness;
- Tiredness;
- Light-headedness;
- Diarrhoea;
- Loss of appetite;
- Abnormal vaginal odour;
- Body aches and pain;

- Fever;
- Dry mouth with thirst.

The symptoms described above can be signs of some of the serious side effects, which have been observed after using LUCRIN DEPOT 11,25 mg PDS. Additional side effects are listed below.

The frequently observed side effects reported in breast cancer, with endometriosis, uterine fibroids and with prostate cancer patients:

Frequent:	appetite increased[a] , nervousness [a, b, c], mood swings[a], difficulty in sleeping [a, b,c,d], feelings of hopelessness and sadness [a b c, d], lack of interest in sex [b c d] , headache [a b c, d], dizziness[a, b, c] , hot flush[a, d], widening of blood vessels[b c], nausea[a, b ,c ,d] , increased sweating[a d], back pain[a, b, d], joint pain [a, b, d], lack of strength and energy [a, b ,c] , weight increased [a, b, c, d], weight decreased[a, b c], injection site induration[a], injection site pain [a,c,d] and feeling hot [a], general physical health deterioration[a], appetite decreased[a], loss of appetite[a, d], vomiting [a,] diarrhoea [a, c] , trouble having a bowel movement [a d], hair loss[a] , erythema[a], sleep disorder[a], difficulty in sleeping[b,c d], dizziness postural[a], forgetfulness[a], pink eye[a] , deafness[a], motion sickness[a], palpitations[a], sputum increased[a], cough[a], the area around the stomach is larger than normal[a], inflammation of the gum[a], inflammation of the lining of the stomach[a], abdominal pain[a, c], acne[a, b], rash[a], eczema[a], vaginal discharge[a], breast pain[a, b], chest pain[a] , swelling [a,b], swelling of legs, feet and arms[d] , application site swelling [d] , skin reactions [b, c,] pain [b,c,d], nervousness [b, c,], anxiety[b], vaginal infection [b, c], disorder affecting nerves and associated muscles [b, c], tingling or numbness in hands or feet [b, c], gastrointestinal disorders [b], excess or unwanted hair growth [b], joint disorders [b, c], pain in

	the muscles [b], breast disorder [b, c], migraine [b], neck pain [b], genital discharge [b], pelvic pain [b], injection site reaction [d], affect lability [c], flatulence [c], chills [c], bone pain [d], urinating a lot at night [d], urination impaired[d], impotence[d], testicular disorder [d], feeling tired [d], bronchitis [d], itching[d], prostatic specific antigen increased[d], asthma [d], urinary tract infection [d], abnormal loss of weight[d], muscular weakness[d], presence of red blood cells in the urine[d].
Less frequent:	upper respiratory tract infection[a], loss of appetite[b], decrease in the number of white blood cells[a], swelling [c], increase appetite[b c], dizziness [d], vomiting [c], nausea and vomiting [c], trouble having a bowel movement [c], hair loss [d], pink eye[c], cough[d], inflammation of the lining of the stomach[d], rash[d], chest pain[c, d], generalised swelling[b], anxiety [c], pain in the muscles [d], migraine [c], pelvic pain [c], infection [b], eye disorder [b], eye pain [b], arthritis [b], face swelling [b], injection site reaction [b], a runny [c], stuffy nose [c], dry mouth [c], , skin odour abnormal [c], nail disorder [c], menstrual disorder [c], injection site mass [c], hypersensitivity [d], tremor [d], chronic obstructive pulmonary disease [d], muscle spasms [d], dry skin[d]

[a] - breast cancer

[b] - endometriosis

[c] - uterine fibroids

[d] - prostate cancer

Some people taking gonadotropin releasing hormone (GnRH) agonists like LUCRIN DEPOT 11,25 mg 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

Other side effects have been observed after taking **LUCRIN DEPOT 11,25 mg PDS**.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LUCRIN DEPOT 11,25 mg PDS.

You can also report side effects to AbbVie (Pty) Ltd via this e-mail address: MEAPV@abbvie.com

5 How to store LUCRIN DEPOT 11,25 mg PDS

Store all medicines out of reach of children.

Store at or below 25 ºC (room temperature).

Do not refrigerate or freeze.

Store in the original container in order to protect from light.

The suspension should be discarded if not used immediately after reconstitution.

Extra diluent is provided. Any unused diluent remaining should be discarded.

6 Contents of the pack and other information

What LUCRIN DEPOT 11,25 mg PDS contains

The active substance is leuprolide acetate. Each single-dose pre-filled dual chamber syringe contains 11,25 mg leuprolide acetate and 1 mL of sterile diluent for injection.

The other ingredients are copolymers (DL-lactic and glycolic acids) and mannitol.

The accompanying diluent contains carboxymethylcellulose sodium, D-mannitol, polysorbate-80, water for injection and acetic acid, glacial (pH adjuster).

What LUCRIN DEPOT 11,25 looks like and the contents of the pack

Each pack contains a single-dose pre-filled dual chamber syringe of LUCRIN DEPOT 11,25 mg PDS and 1 mL of LUCRIN DEPOT DILUENT sterile liquid for reconstitution. The dual chambered syringe consists of a glass cartridge, rubber stopper, the front assembly of the syringe, the finger grip and the plunger rod. The syringe is a colourless silicone-baked cartridge of highly resistant borosilicate glass (Type I glass), with siliconized chlorobutyl rubber stoppers and a stainless steel 23 gauge needle.
LUCRIN DEPOT 11,25 mg PDS is a white powder. The sterile liquid for reconstitution is a clear, colourless liquid. After reconstitution the suspension should appear milky.

Holder of the Certificate of Registration

AbbVie (Pty) Ltd

Building 7

Waterfall Corporate Campus

74 Waterfall Drive

Waterfall City

Midrand

1685

South Africa

Tel: +27 (0)11 031 1600

This leaflet was last revised in

07 October 2025

Registration number

59/21.10/0186

Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com