SCHEDULING STATUS

S4

LUCRIN DEPOT 3,75 Lyophilised microspheres for injection

leuprolide acetate

LUCRIN DEPOT DILUENT Sterile diluent for injection

Contains mannitol (sugar-alcohol)

Read all of this leaflet carefully before you start receiving LUCRIN DEPOT 3,75

- 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 3,75 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 3,75 is and what it is used for**
2. **What you need to know before you use LUCRIN DEPOT 3,75**
3. **How to use LUCRIN DEPOT 3,75**
4. **Possible side effects**
5. **How to store LUCRIN DEPOT 3,75**
6. **Contents of the pack and other information**

1 What LUCRIN DEPOT 3,75 is and what it is used for

LUCRIN DEPOT 3,75 is a GnRH agonist, which inhibits gonadotropin (a hormone) secretion. LUCRIN DEPOT 3,75 is used in men to treat prostate cancer, in women for

the treatment of endometriosis and breast cancer, and in children to treat central precocious puberty.

2 What you need to know before you use LUCRIN DEPOT 3,75

LUCRIN DEPOT 3,75 should not be administered to you:

- If you are hypersensitive (allergic) to GnRH, GnRH agonist analogs 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 3, 75.
- If you are breastfeeding (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

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

- If you engage in sexual intercourse: Although LUCRIN DEPOT 3,75 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 3,75.
- During the first weeks of treatment: You may experience an increase in clinical signs and symptoms during the first few days of therapy. These can be treated by your doctor and may get less with continued therapy.
- If you have a history of or risk factors for QT prolongation or are receiving any medicine that might prolong the QT interval: Please consult your doctor.

In children:

- Bone loss (decreased bone mineral density) may occur during the treatment of early onset of puberty (central precocious puberty) with LUCRIN DEPOT 3,75. However, after the treatment is stopped, bone loss is reversed and may come back to normal levels in late adolescence.

Other medicines and LUCRIN DEPOT 3,75:

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 3,75 in pregnancy has not been established. It is not known if LUCRIN DEPOT 3,75 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 3,75 may make you feel drowsy. It is not always possible to predict to what extent LUCRIN DEPOT 3,75 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 3,75 affects them.

3 How to use LUCRIN DEPOT 3,75

The recommended dose is 3,75 mg given monthly as an intramuscular or subcutaneous injection.

You should periodically change the site where you are given your injection.

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

If you are administered more LUCRIN DEPOT 3,75 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 3,75

If you stop your therapy and after LUCRIN DEPOT 3,75 has cleared your system, you should notice full reversibility of hormone suppression.

4 Possible side effects

LUCRIN DEPOT 3,75 can have side effects.

Not all side effects reported for LUCRIN DEPOT 3,75 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LUCRIN DEPOT 3,75, please consult your health care professional for advice.

Most side effects are mild to moderate however, some may be serious and require treatment.

If you notice any of the following after taking LUCRIN DEPOT 3,75, stop taking LUCRIN DEPOT 3,75 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 3,75:

- Mental impairment including thoughts of suicide or depression;
- Nausea;
- Headaches;
- Dizziness;
- Tiredness;
- Light-headedness;
- Loose stools;
- 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 3,75. Additional side effects are listed below.

The frequently observed side effects reported in **breast cancer** patients:

Frequent:	headache; dizziness; nausea; swelling, redness and pain of the skin; increased sweating; injection site induration; injection site pain and feeling hot; increased appetite; abnormal weight gain; abnormal loss of weight; mood swings; nervousness; difficulty in sleeping; feelings of hopelessness and sadness; hot flushes; joint pain; back pain, general physical health deterioration; fever; common cold; urinary tract infection; iron deficiency anaemia; decreased appetite; sleep disorder; anxiety; vision blurred; cough; trouble having a bowel movement; vomiting; diarrhoea; abdominal pain; bone pain; neck pain; muscular weakness; chest pain; swelling; swelling of legs, feet and arms; feeling tired; injection site reaction
Less frequent:	upper respiratory tract infection, loss of appetite

The frequently observed side effects reported in patients with **endometriosis**:

Frequent:	feelings of hopelessness and sadness; lack of interest in sex; headaches; dizziness; nausea; acne; skin reactions; nervousness; difficulty in sleeping; abnormal weight; widening of blood vessels; vaginal infection; anxiety; abnormal loss of weight; tingling or numbness in hands or feet; gastrointestinal disorder; excess, unwanted hair growth; oily skin appearance; joint disorders; breast disorder; swelling; swelling of legs, feet

	and arms; lack of strength and energy; trouble having a bowel movement; nausea and vomiting; diarrhoea; dry mouth; abdominal pain; neck pain; joint pain; back pain; pain; chest pain; injection site pain; chills; thirst
Less frequent:	infection; loss of appetite; increased appetite; personality disorder; delusion; thinking abnormal; eye disorder; eye pain; the area around the stomach is larger than normal; urinary incontinence; breast enlargement; overly full or swollen breast; face swelling; generalised swelling; injection site reaction

The frequently observed side effects reported in patients with **prostate cancer**:

Frequent:	widening of blood vessels; increased sweating; swelling of legs, feet and arms; problems breathing; nausea; vomiting; impotence; testicular disorder; pain; loss of appetite, lack of interest in sex; diarrhoea; joint pain; injection site pain
Less frequent:	lack of strength and energy; a runny, stuffy nose; abnormal weight gain; difficulty in sleeping; feelings of hopelessness and sadness; ear pain; bone pain; pain in the muscles; chest pain; chills

The frequently observed side effects reported in patients with **central precocious puberty**:

Frequent:	rash; acne; injection site reaction with abscess; pain; growth retardation; abnormal weight gain; headache; widening of blood vessels
Less frequent:	infection; a runny, stuffy nose; influenza; inflammation of the throat; sinusitis; hypersensitivity; precocious puberty; swelling in the thyroid gland; increased appetite; nervousness; feelings of hopelessness and sadness; trouble having a bowel movement; nausea and vomiting; unable to control bladder/urine

Some people taking gonadotropin releasing hormone (GnRH) agonists like LUCRIN DEPOT 3,75 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 3,75.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LUCRIN DEPOT 3,75.

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

5 How to store LUCRIN DEPOT 3,75

Keep medicine out of the reach and sight of children.

Store at room temperature (below 25 ºC).

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 3,75 contains

The active substance is leuprolide acetate. Each single-dose vial contains 3,75 mg leuprolide acetate.

The other ingredients are gelatine, copolymers (DL-lactic and glycolic acids) which control the release of the active ingredient into the body, and mannitol.

The accompanying diluent contains carboxymethylcellulose sodium, D-mannitol, polysorbate-80 and water for injection.

What LUCRIN DEPOT 3,75 looks like and the contents of the pack

Each pack contains a single-dose vial of LUCRIN DEPOT 3,75 and an ampoule of LUCRIN DEPOT DILUENT with 2,0 mL of sterile liquid for reconstitution.
LUCRIN DEPOT 3,75 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

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Access to the corresponding Professional Information

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