

Patient Information Leaflet

SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LEUPROLIDE HEXAL 5 (implant)

Please read this leaflet carefully before using LEUPROLIDE HEXAL 5.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- LEUPROLIDE HEXAL 5 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.

1. WHAT LEUPREOLIDE HEXAL 5 CONTAINS:

Each implant of Leuprolide Hexal 5 contains 5,25 mg of leuprorelin acetate equivalent to 5 mg of leuprorelin.

Other ingredients:

Poly (D,L-lactide)

2. WHAT LEUPROLIDE HEXAL 5 IS USED FOR:

LEUPROLIDE HEXAL 5 is used for treatment of prostate cancer. It works by blocking secretion of hormones from the testes. In some types of cancer, these hormones help the cancer cells to grow.

3. BEFORE YOU ARE GIVEN LEUPROLIDE HEXAL 5:

You should not be given LEUPROLIDE HEXAL 5:

- If you are allergic (hypersensitive) to:
 - leuprorelin acetate,
 - Poly (D,L-lactide),
 - any other medicines, or other substances, such as foods, preservatives or dyes.
- If it has been shown that your prostate cancer is hormone independent.
- If you have had surgical removal of the testicle(s).

Special care should be taken with LEUPROLIDE HEXAL 5:

Tell your doctor or nurse before being given the injection:

- If you have had a cancer that has spread to other organs particularly the spinal cord or the brain.
- If you have urinary tract blockage or hindrance or difficulty passing urine.
- If you have history of convulsions, fits or seizures.
- If you suffer from sugar diabetes.

LEUPROLIDE HEXAL 5 may impair fertility in men.

There is a chance that your bones may become thinner if you use LEUPROLIDE HEXAL 5 for long periods of time. Ask your doctor if this is a risk for you.

LEUPROLIDE HEXAL 5 has not been tested in children, so the safety and effectiveness in children is not known.

Pregnancy and Breastfeeding:

LEUPROLIDE HEXAL 5 is intended for use in male patients only.

Driving and using machinery:

- Do not drive or operate any machinery, especially during initiation (first four weeks) of treatment with LEUPROLIDE HEXAL 5.
- LEUPROLIDE HEXAL 5 may alter reactivity to such an extent that the ability to drive or operate machinery is impaired. This applies to an even greater extent when combined with alcohol.

Using other medicines with LEUPROLIDE HEXAL 5:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

There are no known interactions of LEUPROLIDE HEXAL 5 with other medicines. If you have any questions or concerns, please consult your doctor or pharmacist.

4. HOW LEUPROLIDE HEXAL 5 will be administered to you:

Administration of LEUPROLIDE HEXAL 5 should be performed by a medical practitioner experienced in tumour therapy.

- Your doctor will administer LEUPROLIDE HEXAL 5 into a skin fold in the abdomen.

If you receive more LEUPROLIDE HEXAL 5 than you should:

Since, a healthcare professional will administer LEUPROLIDE HEXAL 5, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for LEUPROLIDE HEXAL 5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LEUPROLIDE HEXAL 5, please consult your doctor or other health care professional for advice.

When LEUPROLIDE HEXAL 5 is first started, there may be a temporary increase in some hormones. This may cause an increase in pain or other symptoms of prostate cancer in the first weeks (first four weeks) of treatment.

Please see your doctor immediately or go to the nearest hospital if the following symptoms occur:

- Swelling of the face, lips, mouth, throat, or neck which may cause difficulty in swallowing or breathing or a sudden collapse.
- Unsteadiness when walking.
- Difficulty or pain when passing urine.
- Blood in your urine.
- Feeling weakness or numbness of lower limbs.
- Swelling in limbs.
- Change in breast size.
- Problems with your eye sight.
- Numbness or tingling of hands or feet.
- Fever, skin rash and itching.

Possible serious side effects may include the following:

Please tell your doctor as soon as possible if you notice any of the following symptoms or they become worse:

- Diarrhoea.

- Nausea/vomiting.
- Cough.
- Unusual tiredness, sleepiness or drowsiness.
- Raised pressure in the skull (a condition of raised pressure within the skull that is not the result of a brain tumour, hydrocephalus, or other obvious cause).
- Hot flushes with sweating bouts and body odour.
- Muscle, back or joint pain.
- Reduction of the size of your testicles, reduced libido and sexual potency.
- Buzzing, hissing, whistling, ringing or other persistent noise in the ear.
- Local skin reactions e.g. pain, reddening and swelling at the site of injection.
- Changes in blood pressure.
- Headache.
- Depressed mood or exacerbation of pre-existing symptoms.
- Dizziness, light-headed or faint when getting out of bed or standing up.

6. STORING AND DISPOSING OF LEUPROLIDE HEXAL 5:

LEUPROLIDE HEXAL 5 should be stored at room temperature (at or below 25 °C).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF LEUPROLIDE HEXAL 5:

Leuprolide Hexal 5 is available in a single dose administration kit containing 1 (one) pre-filled syringe, sealed in an aluminium sachet.

8. IDENTIFICATION OF LEUPROLIDE HEXAL 5:

White to slightly yellowish implant with a uniform surface, one implant in each syringe, sealed in a sachet.

9. REGISTRATION NUMBER:

A40/21.10/0263

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd.¹

72 Steel Road,

Spartan

Kempton Park,

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11. DATE OF PUBLICATION”

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¹ Company Reg. No.: 1990/001979/07