PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LEUPROLIDE HEXAL 5 (implant)

Leuprorelin acetate

Read all of this leaflet carefully before you are given LEUPROLIDE HEXAL 5

- 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.
- 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.

What is in this leaflet

1. What LEUPROLIDE HEXAL 5 is and what it is used for
2. What you need to know before you are given LEUPROLIDE HEXAL 5
3. How LEUPROLIDE HEXAL 5 will be administered to you
4. Possible side effects
5. How to store LEUPROLIDE HEXAL 5
6. Contents of the pack and other information

1. What LEUPROLIDE HEXAL 5 is and what it 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.

2. What you need to know before you are given LEUPROLIDE HEXAL 5

You should not be given LEUPROLIDE HEXAL 5:

- If you are hypersensitive (allergic) to leuprorelin acetate or any of the other ingredients of LEUPROLIDE HEXAL 5 (listed in section 6).
- If it has been shown that your prostate cancer is hormone independent.
- If you have had surgical removal of your testicle(s).

Warnings and precautions

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 diabetes (elevated blood sugar levels). You should be regularly monitored during treatment, as treatment with LEUPROLIDE HEXAL 5 could make your diabetes worse.
- If you have diabetes or suffer from heart problems, you should tell your doctor.
- If you suffer from depression, as treatment with LEUPROLIDE HEXAL 5 may make you more depressed. Speak to your doctor if you suffer from depression.
- There is a chance that your bones may become thinner (osteoporosis) if you use LEUPROLIDE HEXAL 5 for long periods of time. Ask your doctor if this is a risk for you.
- If you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions, talk to your doctor before using LEUPROLIDE HEXAL 5. The risk of heart rhythm problems may increase when using LEUPROLIDE HEXAL 5.

LEUPROLIDE HEXAL 5 may impair fertility in men.

LEUPROLIDE HEXAL 5 may cause liver dysfunction, jaundice (yellowing of the skin and whites of the eyes) and changes to liver enzyme levels in your blood. You will be closely monitored for any signs of liver damage.

Fractures of the spine, paralysis (being unable to move your muscles) and hypotension (low blood pressure) have been reported with the active ingredient in LEUPROLIDE HEXAL 5, leuprorelin acetate.

There have been reports that the active ingredient in LEUPROLIDE HEXAL 5, leuprorelin acetate, may cause seizures (fits) in patients who do not have a history of seizures.

Initial treatment complications

During the first week of treatment, there is generally a brief increase in the male sex hormone testosterone in the blood. This can lead to a temporary worsening in the disease-related symptoms and also to the occurrence of new symptoms that have not been experienced up to this point. These especially include bone pain, urination disturbances, pressure on the spinal cord, pain or weakness, loss of feeling in your legs or swelling due to build-up of tissue fluid. These symptoms usually subside on continuation of treatment. If the symptoms do not subside, you should contact your doctor.

Children and adolescents

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

Other medicines and LEUPROLIDE HEXAL 5

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

LEUPROLIDE HEXAL 5 may interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopyramide, amiodarone, sotalol, dofetilide and ibutilide) or may increase the risk of heart rhythm problems when used together with some other medicines such as methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), and antipsychotic medicines (medicines used to help your brain function normal).

If you have any questions or concerns, please consult your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

LEUPROLIDE HEXAL 5 may cause visual disturbances, dizziness and fatigue (tiredness) and as such may affect your ability to drive or operate machinery. This applies to an even greater extent when combined with alcohol. Do not drive or operate machinery until you know how LEUPROLIDE HEXAL 5 will affect you.

3. 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 health care provider will administer LEUPROLIDE HEXAL 5, he/she will control the dosage. However, if you suspect you have received more than you should, let your doctor know about it immediately so appropriate measures can be taken.

If you forget to use LEUPROLIDE HEXAL 5

It is important not to miss a dose of LEUPROLIDE HEXAL 5. As soon as you realise you have missed an injection, contact your doctor, who will be able to give you your next injection.

If you stop receiving LEUPROLIDE HEXAL 5

Treatment involves administration of LEUPROLIDE HEXAL 5 for a long period, so when the treatment is interrupted, you may experience a worsening of the symptoms related to the disease. Therefore, you must not interrupt the treatment prematurely without your doctor's permission.

4. Possible side effects

LEUPROLIDE HEXAL 5 can have 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 health care provider for advice.

When LEUPROLIDE HEXAL 5 is first started, patients typically experience a brief increase in levels of the male hormone (testosterone) in the blood. This may temporarily worsen symptoms of disease within the first few weeks of treatment, for example:

- Development of or increase in bone pain.
- Difficulty passing urine due to urinary obstruction.
- Spinal cord compression.
- Muscle weakness in the legs.

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
- Problems with your eye sight
- Numbness or tingling of hands or feet
- Fever, skin rash and itching

These are all very serious side effects. If you have them, you may have had a serious reaction to LEUPROLIDE HEXAL 5. You may need urgent medical attention or hospitalisation.

Please tell your doctor if you notice any of the following:

Frequent side effects:

- Weight changes
- Decreased appetite
- Sleep disorders
- Depressed mood
- Mood swings/changes during long term use
- Headache
- Hot flushes
- Nausea/vomiting
- Changes in values for tests of how the liver is working (which may, however, be due to the underlying disease)
- Excessive sweating
- Muscle weakness
- Bone pain or joint pain
- Waking up at night and needing to urinate (nocturia)
- Reduction of the size of your testicles, reduced libido and sexual potency

- Change in breast size (gynaecomastia)
- Unusual tiredness, sleepiness or drowsiness
- Local skin reactions e.g. pain, reddening and swelling at the site of injection
- Increased blood levels of prostate-specific antigen (PSA), which is a substance produced by the prostate gland

Less frequent side effects:

- Dizziness
- If you have an existing pituitary lesion, there may be an increased risk of loss of blood to the area, which may cause permanent damage
- Mood swings/changes during short term use
- Diarrhoea
- Pins and needles sensation (paraesthesia)
- Muscle ache

The frequency of the following side effects are unknown:

- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopaenia)
- Reduction in white blood cells which may lead to more frequent infections (leucopenia)
- Inflammation of lungs, lung disease
- Abnormal levels of lipids (fat) in the blood (shown in a blood test)
- Changes in blood sugar levels
- Seizures (fits)
- Paralysis (being unable to move your muscles)
- Heart palpitations (feels like your heart is beating too hard or too fast)

- Changes seen on an ECG (prolongation of the QT interval) test, which measures the electrical activity of your heart
- Changes in blood pressure (high or low blood pressure)
- Pulmonary embolism (the formation of a blood clot in your lung, resulting in symptoms like breathlessness, difficulty in breathing and chest pain)
- Coughing of blood
- Inflammation of lungs or lung disease
- Yellowing of the skin and whites of the eyes (jaundice)
- Abnormal hair growth
- Fracture of the spine
- Thinning of bone (osteoporosis)
- Testicular pain
- Fever, chills
- Increase in blood calcium and uric acid (shown in a blood test)

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 LEUPROLIDE HEXAL 5.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store LEUPROLIDE HEXAL 5

LEUPROLIDE HEXAL 5 should be stored at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

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).

What LEUPROLIDE HEXAL 5 looks like and contents of the pack

LEUPROLIDE HEXAL 5 is a white to slightly yellowish implant with a uniform surface, one implant in each syringe, sealed in a sachet.

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

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Not applicable.

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