

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

EUPRO 7,5 7,5 mg Lyophilised microspheres for injection

Leuprolide acetate

Contains sugar (mannitol): 13,20 mg per vial lyophilized powder.

Contains sugar (mannitol): 75,0 mg per vial sterile solvent.

Read all of this leaflet carefully before you are given EUPRO 7,5

- 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.

What is in this leaflet

1. What EUPRO 7,5 is and what it is used for
2. What you need to know before you use EUPRO 7,5
3. How to use EUPRO 7,5
4. Possible side effects
5. How to store EUPRO 7,5
6. Contents of the pack and other information

1. What EUPRO 7,5 is and what it is used for

EUPRO 7,5 is a synthetic hormone which can be used to reduce the levels of testosterone produced by the testicles.

It is used to treat prostate cancer in men.

Testosterone appears to be needed by prostate cancer cells. When the body's supplement of testosterone is low, prostate cancer shrinks.

By lowering the amount of testosterone, EUPRO 7,5 may help relieve the pain, urinary problems and other prostate cancer related symptoms.

However, EUPRO 7,5 is not a cure for prostate cancer. Your body will start producing testosterone again, once treatment with EUPRO 7,5 is stopped.

2. What you need to know before you EUPRO 7,5

EUPRO 7,5 should not be administered to you:

- if you are hypersensitive (allergic) to leuprolide acetate, similar medicine, the other ingredients of EUPRO 7,5 (listed in section 6), or to synthetic gonadotropin releasing hormones or derivatives.
- if you are a woman or a child.
- if you underwent a surgical procedure known as orchiectomy (a procedure where one or both testicles are removed).
- if you are being treated with EUPRO 7,5 only, and suffer from spinal cord compression, or have been diagnosed to have cancer of the spine.

Warnings and precautions

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

- if you suffer from heart problems.
- if you suffer from urinary obstruction or spinal cord compression. Your doctor will supervise you closely for the first few weeks of treatment.
- if you are a man with prostate cancer, and have had injections of a synthetic hormone in the past that has not worked, or you have had an operation to remove your testicles.
- if you have any of the following: Any heart or blood vessel conditions, including heart rhythm problems (dysrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using

EUPRO 7,5.

- if you are at an increased risk of thinning of the bones (osteoporosis) you should tell your doctor before taking EUPRO 7,5. Risk factors include:
 - If you or any of your close family have thinning of the bones.
 - If you drink excessive amounts of alcohol, and/or smoke heavily.
- if you are diabetic, EUPRO 7,5 can aggravate existing diabetes therefore, you may need more frequent monitoring of your blood glucose levels.
- if you are experiencing seizures, have a history of seizures (convulsions), seizure disorders or have a high risk of developing seizures, you should inform your doctor.

Children

Do not give EUPRO 7,5 to children as it is unlikely to be safe.

Other medicines and EUPRO 7,5

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

EUPRO 7,5 might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopramide, amiodarone, sotalol, dofetilide, ibutilide) or might increase the risk of heart rhythm problems when used with some other medicines (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Leuprolide acetate can suppress the pituitary-gonadal system (gland in the brain that is responsible for the production of reproductive hormones such as FSH and LH). This might result in inaccurate diagnostic test results during therapy.

EUPRO 7,5 with food and drink

EUPRO 7,5 can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

EUPRO 7,5 must not be administered to women, especially to pregnant or breastfeeding women.

Driving and using machines

Do not drive or operate machinery if you experience drowsiness, dizziness or visual disturbances whilst being treated with EUPRO 7,5.

It is not always possible to predict to what extent EUPRO 7,5 may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which EUPRO 7,5 affects you.

3. How to use EUPRO 7,5

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

Route of administration: subcutaneous.

You will not be expected to give yourself EUPRO 7,5. It will be given to you by a person who is qualified to do so.

The injection will normally be given in your arm, thigh or abdomen. The injection site should be varied at regular intervals.

You will normally be given an injection once every month.

If you take use more EUPRO 7,5 than you should

Since a healthcare professional will administer EUPRO 7,5, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of EUPRO 7,5

Since a healthcare professional will administer EUPRO 7,5, it is unlikely that the dose will be missed.

If you stop taking EUPRO 7,5

EUPRO 7,5 is a synthetic hormone which can be used to reduce the levels of testosterone produced by the testicles. When the body's supplement of testosterone is low, prostate cancer shrinks.

By lowering the amount of testosterone, EUPRO 7,5 may help relieve the pain, urinary problems and other prostate cancer related symptoms.

However, if treatment with EUPRO 7,5 is stopped, your cancer related symptoms may return, as the cancer growth will return.

4. Possible side effects

EUPRO 7,5 can have side effects.

Not all side effects reported for EUPRO 7,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EUPRO 7,5, please consult your health care provider for advice.

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If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- sever rash,
- itching,
- shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to EUPRO 7,5. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you feel changes in the way your heart beats.
- If you suffer from any unexplained bruising or bleeding or feel generally unwell whilst taking EUPRO 7,5. Although rare, these could be symptoms of changes in the number of red or white blood cells.

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

Tell your doctor if you notice any of the following:

- When men with prostate cancer first start treatment with EUPRO 7,5, levels of testosterone can increase and in some people this may cause a temporary increase in local pain. In some cases, to prevent this from happening, your doctor may give you another type of medicine (anti-androgen medicine) before and just after your first EUPRO 7,5 injection. If you do get worsening pain, weakness or loss of feeling in your legs or difficulty passing urine, contact your doctor immediately.
- There may be an increased risk of loss of blood to the pituitary area (if you have an existing pituitary lesion), which may cause permanent damage.
- Blood sugar levels may be altered during treatment with EUPRO 7,5, which may affect control in diabetic patients and require more frequent monitoring.

Frequent side effects:

- upper respiratory tract infection (also known as the common cold or nasopharyngitis),
- blood tests may show anaemia (low red cell counts), low counts in white cells or platelets,
- hot flushes,
- nausea, constipation, dry mouth, vomiting, diarrhoea,
- bruising, redness of the skin, itching,
- night sweats,
- joint pain, limb pain, muscle pain,
- weakness,
- feeling cold (with shivers),
- urinating difficulty, painful urination, low urine volume, frequently urinating at night,
- a reduction in size and function of the testes and or penis,

- swelling of the breast tissue, breast tenderness,
- testicular pain,
- low sperm count,
- tiredness,
- skin reactions at the injection site (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers, skin damage),
- feeling unwell,
- abnormal bleeding (due to changes in the blood clotting time).

Less frequent side effects:

- urinary tract infection,
- localised skin infection,
- increase in blood sugar level (due to aggravated diabetes mellitus),
- abnormal dreams,
- depression,
- decreased sex drive,
- dizziness,
- difficulty sleeping,
- headache,
- taste and smell disturbance,
- abnormal involuntary movements,
- high or low blood pressure,
- fainting,
- unconsciousness,
- runny nose,
- difficulty breathing,
- passing of wind,
- burping or passing of wind from the mouth,

- moistened or wet hands,
- increased sweating,
- hair loss (alopecia),
- skin outbreak (causing red, bumpy, scaly or itch patches of skin),
- back pain,
- muscle cramps,
- spasm of the bladder,
- blood in the urine,
- intense need to urinate more frequently,
- incomplete emptying of the bladder,
- breast pain,
- breast development in men,
- inability to achieve an erection or orgasm,
- changes to testicles,
- itching at the injection site,
- hardening of the injection site,
- lack of energy,
- pain at the injection site,
- fever,
- blistering and tenderness at the injection site,
- weight increase,
- abnormalities in liver function or liver blood tests,
- increase in the number of fats (lipids) in the blood (known as triglycerides),

Side effects with an unknown frequency:

- a low number of platelets in the blood (thrombocytopenia), low level of white blood cells in the blood, which can interfere with the ability to fight infections (leucopenia),
- severe, potentially life-threatening allergic reaction,

- memory loss,
- seizures,
- death of an area of tissue in the pituitary gland (gland in the brain) known as pituitary apoplexy,
- visual disturbances,
- changes in the way your heart beats (also known as QT-prolongation), detected on an electrocardiogram (ECG),
- increase in heartbeat,
- swelling of the lower legs or hands due to circulation problems associated with underlying conditions such as heart or renal failure (also known as peripheral oedema),
- lung disease (known as interstitial lung disease).
- blood clot in the lung (also known as pulmonary embolism),
- tingling, numbness or pricking sensation of the skin, chills or rash,
- lack of physical activity due to muscle atrophy (when muscles waste away).

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 or nurse. This includes any possible side effects not listed in this leaflet. 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 EUPRO 7,5.

5. How to store EUPRO 7,5

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Protect from light.

Reconstituted suspension: Since EUPRO 7,5 microspheres and their solvent contains no preservative, the reconstituted suspension should be used immediately after preparation and any unused portion should be discarded.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Discard the needle in an appropriate manner (i.e. medical sharps waste bin).

6. Contents of the pack and other information

What EUPRO 7,5 contains

The active substance is leuprolide acetate.

The other ingredients are carmellose sodium 30 cps, gelatin, mannitol, polylactic acid (PLA), polysorbate 80 and water for injection.

What EUPRO 7,5 looks like and contents of the pack

Powder and solvent for suspension for injection.

Powder

White powder without discoloration or superficial foreign particles.

Single dose administration kit containing one 6 mL clear type I glass vial, with a 20 mm dark grey rubber stopper and aluminium crimp cap with blue plastic flip cap; 1 solvent ampoule; 1 disposable syringe and two 22 G 1½ needles.

Solvent

Limpid, colourless liquid, without suspended particles.

3 mL colourless glass ampoule type I with a nominal volume of 2 mL, with a breakage ring and specified dimensions, is used.

Holder of Certificate of Registration

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