Approved Patient Information Leaflet

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

GENPROLEX Injection

(Leuprolide acetate)

Read all of this leaflet carefully before you use GENPROLEX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.

GENPROLEX 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 GENPROLEX is and what it is used for

GENPROLEX belongs to a group of medicines called Gonadotropin releasing hormones.

GENPROLEX is used to treat the symptoms of advanced prostate cancer.

2. What you need to know before you use GENPROLEX

Do not take GENPROLEX:

- If you are hypersensitive (allergic) to Leuprolide acetate or any of the ingredients of **GENPROLEX** (listed in section 6);

Although **GENPROLEX** is not indicated for use in women, **GENPROLEX**, it should also not be used if:

- you are or may become pregnant while receiving **GENPROLEX**;
- you are breastfeeding;
- you have undiagnosed, abnormal vaginal bleeding.

Warnings and precautions

Tell your doctor or healthcare professional before using **GENPROLEX**:

If you:

- have any heart conditions or abnormalities;
- are taking any medication for your heart such as quinidine, procainamide, amiodarone, sotalol;

- are allergic to benzyl alcohol;
- have a blockage of the urinary tract;
- have any disease of the spine

Special care should be taken with **GENPROLEX**:

- as it may affect the accuracy of some laboratory tests. Always tell your doctor that you are using **GENPROLEX**;
- as it could cause seizures;
- as it could cause a decrease in the density of your bones;
- as it could increase the risk of developing diabetes;
- as it could cause heart problems;
- as it could cause your symptoms to increase for a while.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children and adolescents

GENPROLEX has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and GENPROLEX:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

The use of **GENPROLEX** with these medicines may cause undesirable interactions.

If you are to have any laboratory tests, please tell your doctor that you are using **GENPROLEX**, in particular if they are hormone tests. **GENPROLEX** could affect the results of these tests even for three months after you stop using **GENPROLEX**.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before using this medicine.

GENPROLEX could affect the fertility of males.

Driving and using machines

GENPROLEX might cause low blood pressure, dizziness or blurred vision. Do not drive or operate tools or machines if you experience such side effects.

It is not always possible to predict to what extent **GENPROLEX** 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 **GENPROLEX** affects them.

GENPROLEX contains Benzyl alcohol.

Ask your doctor or pharmacist for advise if you have a kidney or liver disease. This is because large amounts of benzyl alcohol can build-up in your body and may case side effects (called ‘metabolic acidosis’)

3. How to take GENPROLEX

Do not share medicines prescribed for you with any other person. Always use **GENPROLEX** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is an injection of 0,2 mL (1 mg of Leuprolide acetate) given subcutaneously (under the skin) once a day.

Your doctor will tell you how long your treatment with **GENPROLEX** will last. Do not stop any treatment unless your doctor tells you to do so.

If you have the impression that the effect of **GENPROLEX** is too strong or too weak, tell your doctor or pharmacist.

Directions for using GENPROLEX

a) Wash hands thoroughly with soap and water

b) Remove the plastic cover on the bottle to expose the rubber stopper. Wipe the metal ring and rubber stopper with an alcohol swab each time you use **GENPROLEX**. Check the liquid in the container. If it is not clear or has particles in it, DO NOT USE. Exchange it at your pharmacy for another container.

c) Pull the plunger of the syringe back until the plunger tip is at the 0,2 mL (20 unit) mark.

d) Push the needle through the centre of the rubber stopper on the

GENPROLEX bottle.

e) Push the plunger all the way in to expel air into the bottle.

f) Invert the bottle and syringe. Check to make sure the tip of the needle is in the liquid. Pull the plunger slowly backwards until the syringe fills to the 0,2 mL (20 unit) mark.

g) Ensure that no air bubbles are in the syringe. If air bubbles are present, push the plunger forward to expel air into the bottle and refill the syringe to the 0,2 mL (20 unit) mark.

h) Remove the needle from the bottle. DO NOT TOUCH THE NEEDLE OR ALLOW THE NEEDLE TO TOUCH ANY SURFACE.

i) Wipe the injection site with an alcohol swab.

j) Hold the syringe in one hand. Hold the skin taut or pull up a little skin, if needed, with the other hand.

k) Hold the syringe alongside the skin and slide the needle quickly just

under the skin as far as it will go at a 90° angle. Inject the drug by

pushing the plunger.

l) Hold an alcohol swab on your skin where the needle was inserted and

pull the needle at the same angle as it was inserted.

m) To protect you skin, inject each daily dose in a different spot.

n) Use the disposable syringe only once and dispose of it carefully.

As with other medicines administered long-term by subcutaneous injection, the injection site should be regularly varied.

If you take more GENPROLEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take GENPROLEX

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

GENPROLEX can have side effects.

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

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

- Swelling around the eyes or face or tongue, (which may rarely be a serious allergic reaction)
- Swelling in the ankles, wrists, arms and legs
- Difficulty breathing

- Sudden headache, confusion, vomiting, visual changes

These are all very serious side effects. If you have them, you may have had a serious reaction to **GENPROLEX**. You may need urgent medical attention or hospitalisation.
Treatment with **GENPROLEX** can very commonly make your prostate cancer symptoms worse when you first start treatment.

It can also commonly cause headache, muscle weakness, low blood pressure, dry skin, rash, changes in hair growth, hot flushes (a sudden wave of mild or intense body heat), sweating or clamminess, breast tenderness, pain, or change in breast size in both men and women, pain or decrease in size of testicles, swelling of the penis, decrease in sexual ability or desire, pain, burning, or tingling in the hands or feet, change in weight, dry mouth.

Frequent side effects:
Weight gain, Weight loss, Anorexia (loss of appetite),
Lack of interest in sex, increase in the desire for sex,
Headache, muscle weakness, dizziness, tingling or numbness in the hands or feet, a lack of energy, sleepiness, difficulty in sleeping, taste disorder, numbness of upper arm, problems with memory
Blurred vision
Heart failure, irregular heart rhythm, heart attack
Hot flushes, low blood pressure, the dilatation of blood vessels which decreases blood pressure,
Nausea, vomiting, diarrhoea, constipation, swollen stomach, bleeding in the gastrointestinal

tract,

Discolouration of the skin, redding of the skin, hair loss, dry skin, rash, excessive sweating, itchy rash or hives, abnormal hair growth, hair disorder, night sweats, changes in hair growth (little or no hair growth on the head, eyebrows or edge of eye lids), cold sweats, abnormal growth of hair on a woman's face and body

Bone pain, bone swelling, muscle pain,

Blood in urine

Enlarged breast, breast tenderness, decrease in size of testicles, swelling of the penis, pain in testicles, penile blister,

Dry mouth, pain, fever, fluid retention, weakness

Prostatic specific antigen increased, thinning of bone, high blood sugar, high blood cholesterol and triglycerides, increased bone weakness, anaemia (low count of red blood cells), blood urea increased, blood creatinine increased

Frequency not known:

Urinary tract infections, sore throat, inflammation of the lungs, skin cancer, anaemia, allergic reactions

Goitre (a lump or swelling at the front of the neck caused by a swollen thyroid), bleeding of the pituitary gland,

Diabetes mellitus, increased appetite, low blood sugar, dehydration, high levels of phosphate in the blood, low levels of protein in the blood, high levels of fat particles (lipids) in the blood,

Mood swings, nervousness, decrease in sex drive, difficulty sleeping, sleep disorder, depression, anxiety, delusion, suicide thoughts,

Dizziness, headache, memory impairment, taste disorder, a lack of energy, A decreased sense of touch or sensation, temporal loss of consciousness (caused by fall inn blood pressure), Weakness, numbness and pain from nerve damage, usually in the hands and feet, stoke, paralysis, convulsions,

blurred vision, eye disorder, dry eyes, altered vision,

ringing in the ears or loss of hearing

heart failure, heart attack, change in heart beat, sudden cardiac death,

swelling, high blood pressure, low blood pressure, inflammation of a vein, blood clotting, enlarged veins on the legs and feet,

Pleural rub (an audible raspy breathing sound), difficulty breathing, cough, respiratory disorder, nose bleeds, damaged or scared lung tissue, coughing up blood, a build-up of fluid between the tissues that line the lungs and the chest, lung infiltration (substance dense than air in lung surface area), sinus congestion, a sudden blockage of a blood vessel in the lung, inflames and damaged lung tissue

Constipation, nausea, vomiting, bleeding in the stomach, swollen stomach, dry mouth taste disturbance, sores in the lining of the stomach (ulcer), sores in the lining of the duodenum (ulcer), tissue growths in the rectum

Abnormal liver function, jaundice (yellow colour to the skin and eyes),

Hair loss, rash, dry skin, pigmentation disorder (discoloration of the skin), itchy rash or hives, skin disorder, itching, sensitivity to light,

Bone swelling, muscle weakness, joint pain, reduced movement in the spine, tenosynovitis (inflammation and swelling of a tendon),

bladder spasm, unable to control bladder, urge to urinate, abnormally frequent urination,

urinary tract obstruction,

Enlarged breast, breast tenderness, decrease in size of testicles, swelling of the penis, pain in testicles,

Pain, fluid retention, fever, reaction, pain, swelling, puss-forming infection, bruising, hard subcutaneous lumps at injection site

blood urea increased, blood creatinine increased, increased blood uric acid, increased blood calcium, abnormal electrocardiogram, abnormal liver function, decreased blood potassium, increased white blood cell count, decreased white blood cell count, prolonged prothrombin time (blood takes too long to form a clot), cardiac murmur (a blowing, whooshing, or rasping sound heard during a heartbeat), increased blood bilirubin, increased low density lipoprotein, increased blood triglycerides

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **GENPROLEX**.

5. How to store GENPROLEX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

GENPROLEX will be stored in the pharmacy

Store at or below 25 °C.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the vial and the carton.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What GENPROLEX contains

The active substance is Leuprolide Acetate

Each 1 mL contains 5,0 mg of leuprolide acetate and 9,0 mg benzyl alcohol as a preservative.

The other ingredients of **GENPROLEX** are sodium chloride, benzyl alcohol, glacial acetic acid, sodium hydroxide, water for injection.

What GENPROLEX looks like and contents of the pack

GENPROLEX is a clear colourless solution, essentially free from visible particles for subcutaneous injection.

GENPROLEX is supplied in a multi-use glass vial Tubular Type-I, 6R clear BB vial with 20 mm neck, stoppered with 20 mm grey bromobutyl rubber stopper and sealed with aluminium seal having sky blue colour PP disc. The Vial is packed in pre-printed carton with package leaflet

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

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