PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TRELSTAR LA 3,75 mg powder for prolonged-release suspension for Injection

TRELSTAR LA 11,25 mg powder for prolonged-release suspension for injection

TRELSTAR LA 22,5 mg powder for prolonged-release suspension for injection

Triptorelin

Contains sugar (mannitol)

TRELSTAR LA 3,75 mg contains 71 mg mannitol per dose

TRELSTAR LA 11,25 mg contains 74 mg mannitol per dose

TRELSTAR LA 22,5 mg contains 74 mg mannitol per dose

Read all of this leaflet carefully before you are given TRELSTAR LA

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

What is in this leaflet

6. Contents of the pack and other information

1 What TRELSTAR LA is and what is is used for

TRELSTAR LA contains triptorelin, which is similar to a hormone called gonadotropin releasing hormone (GnRH analogue).

It acts by lowering the levels of the male hormone, testosterone, in the body.

TRELSTAR LA is used to treat locally advanced, hormone-dependent prostate cancer. It is also used to treat hormone-dependent prostate cancer which has spread to other parts of the body (metastatic cancer).

TRELSTAR LA is an alternative treatment to orchiectomy or the administration of oestrogens, when those treatments are not indicated or are unacceptable to the patient.

It is a long acting formulation designed to slowly deliver triptorelin:

- TRELSTAR LA 3,75 mg slowly delivers 3,75 mg of triptorelin over a 1-month period (four weeks).
- TRELSTAR LA 11,25 mg slowly delivers 11,25 mg of triptorelin over a 3-month period (twelve weeks).
- TRELSTAR LA 22,5 mg slowly delivers 22,5 mg of triptorelin over a 6-month period (twenty four weeks).

2. What you need to know before you use TRELSTAR LA

TRELSTAR LA should not be administered to you:

- if you are allergic (hypersensitive) to triptorelin embonate, gonadotropin releasing hormone (GnRH), other GnRH analogues or any of the excipients of TRELSTAR LA;
- if you have spinal cord compression (symptoms may include numbness, pain, and weakness) or have metastases in the spinal column;

- if you previously had hormonal therapy which failed;
- if you have hormone independent prostate carcinoma;
- if you had surgical castration;
- If you are a woman.

Warnings and precautions

Tell your doctor if any of the following applies to you:

- if you develop a depressed mood while you are treated with TRELSTAR LA. There have been reports of depression (sometimes severe) in patients receiving TRELSTAR LA (see "Possible side effects");
- if you are a heavy drinker, a smoker, have a family history of osteoporosis (a condition that affects the strength of your bones), have a poor diet or take anticonvulsants (medicines for epilepsy or fits) or corticosteroids (steroids), TRELSTAR LA may, as with other GnRH analogues, lead to bone loss, osteoporosis and a higher risk of bone fractures;
- if the symptoms of the cancer get worse at the beginning of the treatment (when there will be an increased amount of testosterone in your body). Your doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse;
- if you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with TRELSTAR LA. Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes;
- if you have diabetes or if you suffer from heart or vascular problems.
- if you have any heart rhythm problems (dysrhythmia), or if you are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using TRELSTAR LA.

- if you are using medicines for preventing your blood clotting, since you may experience bruising at the site of injection with intramuscular injection.
- if you have problems urinating or with your bowels. During the first weeks of treatment, TRELSTAR LA may, as with other GnRH analogues, in isolated cases, cause the spinal cord to compress, or the urethra (where you pass urine) to block. Your doctor will monitor you and treat you for these conditions if they occur.
- if you have porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin).

Diagnostic tests of pituitary gonadal function conducted during treatment or after discontinuation of therapy with TRELSTAR LA may be misleading.

Please talk to you doctor if you are concerned about any of the above.

Other medicines and TRELSTAR LA

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

This includes complementary or traditional medicines.

TRELSTAR LA might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) 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 substance addiction detoxification), moxifloxacin (an antibiotic), antipsychotics (used for serious mental illnesses)).

Also tell your doctor if you take:

- spironolactone (a “water” tablet)
- levodopa (a medicine for Parkinson’s disease)
- phenothiazines (medicines used for serious mental and emotional disorders)

- dopamine antagonists (such as haloperidol and risperidone, used for certain mental disorders)
- digoxin (heart medicine)
- sex hormones.

Pregnancy, breastfeeding and fertility

TRELSTAR LA is not indicated for use in women.

Driving and using machines

TRELSTAR LA may affect your reactions to such an extent that the ability to drive or to operate machines is impaired. This is particularly true in combination with alcohol. You may feel dizzy, tired or have problems with your sight such as blurred vision.

Do not drive or use machines if you experience any of these side effects.

TRELSTAR LA contains sodium

TRELSTAR LA contains less than 1 mmol (23 mg) sodium per vial. TRELSTAR LA is therefore almost “sodium-free” and may be taken with a low sodium diet.

3. How to use TRELSTAR LA

Due to different release characteristics, the dosage strengths are not additive and must not be used together.

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

You will not be expected to give yourself TRELSTAR LA. It will be given to you by a person who is qualified to do so, under the supervision of your doctor.

Your healthcare provider will reconstitute the powder for injection with the diluent. It is for single use only; any unused portion will be discarded.

Therapy of prostate cancer with TRELSTAR LA requires long term treatment.

Your doctor will tell you how long your treatment with TRELSTAR LA will last.

- TRELSTAR LA 3,75 mg: The usual dose is 1 vial injected subcutaneously (under the skin) or intramuscularly (into the muscle) once a month (every 4 weeks).
- TRELSTAR LA 11,25: The usual dose is 1 vial injected into the muscle every three months (every 12 weeks).
- TRELSTAR LA 22,5 mg: The usual dose is 1 vial injected into the muscle every six months (every 24 weeks).

Your doctor may order blood tests to see how effective the treatment is.

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you receive more TRELSTAR LA than you should

Since a healthcare provider will administer TRELSTAR LA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TRELSTAR LA

Since a healthcare provider will administer TRELSTAR LA, it is unlikely that the dose will be missed.

4. Possible side effects

TRELSTAR LA can have side effects.

Not all side effects reproted for TRELSTAR LA are included in this leaflet. Should your general health worsen of if you experience any untoward effects while receiving TRELSTAR LA, please consult your doctor, pharmacist or other healthcare professional for advice.

The most commonly observed adverse events related to TRELSTAR LA treatment included hot flushes, impotence and decreased libido. Increased lymphocyte count has been reported with patients undergoing GnRH analogue treatment, such as TRELSTAR LA.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing may occur rarely (in more than 1 in 10 000 patients).

You may have a serious allergic reaction to TRELSTAR LA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pins and needles sensation in the legs
- Excessive sweating
- Back pain
- Hot flushes
- Weakness
- Dizziness, headache
- Impotence, loss of libido
- Depression, mood changes (see “Warnings and precautions”)
- High blood pressure
- Nausea
- Tiredness, redness, bruising and/or pain at the injection site, muscle and bone pain, pain in the arms and legs, oedema (build up of fluid in the body tissues)

Less frequent side effects:

- Loss of appetite, gout (severe pain and swelling in the joints usually in the big toe)
- Increase in appetite
- Ringing in the ears
- Tingling or numbness
- Inability to sleep, irritability
- Pain in abdomen, constipation, diarrhoea, vomiting
- Joint pain, muscle cramp, muscle weakness, muscle pain
- Development of enlarged breasts in men, breast pain, reduction in testicular size, pain in testicles
- Difficulty in breathing
- Acne, hair loss, itching, rash
- Drowsiness, shaking, sleepiness, pain
- Some blood tests affected (including raised liver function tests)
- Increase in weight
- Red or purple discolorations on the skin
- Diabetes
- Vertigo, difficuty in standing
- Abnormal sensation in the eye, blurring or disturbance in vision
- Infection of the nose/throat
- Memory loss
- Feeling confused, decreased activity, having a feeling of elation or well-being
- Sensation of fullness in the abdomen, flatulence, dry mouth, abnormal sense of taste
- Stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis
- Inability to ejaculate
- Shortness of breath when lying flat

- Blisters
- Nosebleeds
- Low blood pressure
- Chest pain
- Flu-like symptoms, fever
- Increased body temperature
- Weight loss

Frequency unknown:

- Blurred vision, blood pressure increased, change in ECG (QT prolongation), general discomfort, bone pain, anxiety, convulsions and rapid formation of wheals due to swelling of the skin or mucous membranes.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

5. How to store TRELSTAR LA

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original packaging.

Do not use TRELSTAR LA after the expiry date which is stated on the box and on the labels after EXP. The expiry date refers to the last day of that month.

The reconstituted suspension is for single use only and must be used immediately. Any unused portion must be discarded.

6. Contents of the pack and other information

What TRELSTAR LA contains

The active substance is triptorelin.

TRELSTAR LA 3,75 mg: Each vial contains triptorelin embonate equivalent to 3,75 mg triptorelin. After reconstitution in 2 ml water for injection, 1 ml of reconstituted suspension contains 1,875 mg of triptorelin.

TRELSTAR LA 11,25 mg: Each vial contains triptorelin embonate equivalent to 11,25 mg of triptorelin. After reconstitution in 2 ml water for injection, 1 ml of reconstituted suspension contains 5,625 mg of triptorelin.

TRELSTAR LA 22,5 mg: Each vial contains triptorelin embonate equivalent to 22,5 mg triptorelin. After reconstitution in 2 ml water for injection, 1 ml of reconstituted suspension contains 11,25 mg of triptorelin.

The other ingredients are:

Carmellose sodium, mannitol, poly(d,l-lactide-co-glycolide), polysorbate 80.

What TRELSTAR LA looks like and contents of the pack

TRELSTAR LA is a white to slightly yellow compact powder.

The prepared injection is a milky suspension without aggregates and the total volume passes through an injection needle.

TRELSTAR LA 3,75 mg: 6 ml tinted Type 1 glass vial closed with a 20 mm grey bromobutyl rubber type 1 stopper with an aluminium seal and purple flip-off plastic cap.

TRELSTAR LA 11,25 mg: 6 ml tinted Type 1 glass vial closed with a 20 mm grey bromobutyl rubber type 1 stopper with an aluminium seal and yellow green plastic flip-off plastic cap.

TRELSTAR LA 22,5 mg: 6 ml tinted Type 1 glass vial closed with a 20 mm grey bromobutyl rubber type 1 stopper with an aluminium seal and dark green flip-off plastic cap.

Each box contains 1 or 3 vials.

Not all pack sizes may necessarily be marketed.

Holder of Certificate of Registration

Pharmacare Limited

Healthcare Park

Woodlands drive

Woodmead, 2191

This leaflet was last revised in

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Registration numbers

TRELSTAR LA 3,75 mg: 52/21.12/0034

TRELSTAR LA 11,25 mg: 52/21.12/0035

TRELSTAR LA 22,5 mg: 52/21.12/0036

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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