Title:	Staladex PIL	*Colours (Printed)*	*Colours (Non printed)*
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Package leaflet: Information for the patient

Staladex 11.25 mg Implant

Leuprorelin acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Staladex is and what it is used for

The active substance in Staladex is leuprorelin. Leuprorelin is a synthetic hormone which can be used to reduce the levels of the male sex hormone, testosterone, that is circulating in the body.

Staladex is used in adult men to treat prostate cancer.

2. What you need to know before you use Staladex

Do not use Staladex:
- if you are allergic to leuprorelin, other synthetic hormones, or to any of the other ingredients of this medicine (listed in section 6).
- following surgical removal of your testes (as use of Staladex will not lead to a further decrease in testosterone levels).
- if you are a woman or a child.
- as the only treatment for prostate cancer if the spinal cord is compressed or the cancer has spread to the spine.

Warnings and precautions
Talk to your doctor or nurse before using Staladex:

- if you suffer from a bad or recurrent headache, problems with your eyesight and ringing or buzzing in the ears contact your doctor immediately.
- if you know that you have high blood pressure.
- 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 Staladex. The risk of heart rhythm problems may increase when using Staladex.
- if, before the start of treatment, you already have nervous system symptoms (the spinal cord is compressed or the cancer has spread to the spinal cord) or problems when passing urine due to urinary obstruction. You should tell your doctor without delay; they will monitor you particularly closely for the first few weeks, if possible in hospital.
- if symptoms of disease (such as pain, difficulty passing urine or weakness in the legs) come back after prolonged use of Staladex. If this happens, your doctor will regularly check the success of the treatment by doing clinical examinations and by running laboratory tests.
- if you are at an increased risk of thinning of the bones (osteoporosis).
- if you experience sudden headache, vomiting, altered mental status and sometimes heart collapse, within two weeks of taking Staladex, then alert the doctor or medical staff. These are rare cases termed as pituitary apoplexy, which have been reported in other medicines which work in a similar way to Staladex.
- if you suffer from diabetes (elevated blood sugar levels). You should be regularly monitored during treatment.
- if you develop any of the following after being treated with Staladex, inform your doctor:
  - an abscess at the injection site,
  - yellowing of the skin or whites of the eyes (jaundice) or other liver problems.
  - depressed mood.
  - 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, or the secretion of blood in the urine. These symptoms usually subside on continuation of treatment. If the symptoms do not subside, you should contact your doctor.

If Staladex does not help
A proportion of patients will have tumours which are not sensitive to decreased serum testosterone levels. Please talk to you doctor if you have the impression that the effect of Staladex is too weak.

Effects of misuse for doping purposes
The use of Staladex can produce positive results in doping tests.

Other medicines and Staladex
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Staladex may interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) 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), antipsychotics (used for serious mental illnesses).

Pregnancy, breast-feeding and fertility
Staladex is not intended for use in women.

Driving and using machines
Fatigue (tiredness) is common, particularly at the start of treatment, and may also be due to the underlying cancer. Visual disturbances and dizziness can also occur during treatment. If affected, you should not drive or operate machinery.

3. How to use Staladex

<u>Staladex should only be administered by your doctor or a nurse.</u>

Staladex is injected under the skin of the abdomen once every three months.

The therapy is a long-term treatment, adjusted individually. Please arrange with your doctor that Staladex is administered as precisely as possible in regular 3-monthly periods. An exceptional delay of the injection date for a few days (90 ± 2 days) does not influence the result of the therapy.

If you receive more Staladex than you should
This is unlikely as your doctor or nurse will know the correct dosage. However, if you suspect you have received more than you should, let your doctor know about it immediately.

If you miss a dose of Staladex
It is important not to miss a dose of Staladex. 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 Staladex
Your treatment will be for a long period, so when the treatment is stopped you may experience a worsening of the symptoms due to the disease. You must not stop your treatment prematurely without your doctor's permission.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor immediately or go to hospital:
- If you develop a severe rash, itching or shortness of breath or difficulty breathing. These could be symptoms of a severe allergic reaction.

Tell your doctor:
- If you get a severe headache which does not get better when you take painkillers.
- If you suffer from any unexplained bruising or bleeding or feel generally unwell whilst taking Staladex. Although rare, these could be symptoms of changes in the number of red or white blood cells.

If any of the following side effects get serious, or if you notice any side effects not listed in this leaflet, speak to your doctor or pharmacist:

- When you first start treatment with Staladex, 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 drug such as cyproterone acetate or flutamide before and just after your first injection. If you do get worsening pain, weakness or loss of feeling in your legs or difficulty passing urine, contact your doctor immediately.

- 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. This is very rare (may affect more than 1 in 10,000 people).

- Blood sugar levels may be altered during treatment with Staladex, which may affect control in diabetic patients and require more frequent monitoring.

- If you have a blood test your doctor may notice a change in blood lipid (cholesterol) levels or in values for tests on how the liver is working. These changes do not usually cause any symptoms.

As treatment is continued, the concentration of testosterone will fall to very low levels, causing some patients to experience one or more of the following side effects:

Very common (may affect more than 1 in 10 people):
- weight changes
- hot flushes
- sweating
- muscle weakness
- bone pain
- loss of interest in sexual intercourse
- inability to have an erection
- a reduction in size and function of the testes
- tiredness or skin reactions at the injection site (these include skin hardening, redness, pain, abscesses, swelling, nodules, ulcers and skin damage).

Common (may affect 1 to 10 in 100 people):
- loss of appetite
- difficulty sleeping
- depression
- mood changes (with long-term use)
- headache
- nausea
- abnormalities in liver function or liver blood tests
- joint pain
- swelling of the breast tissue or swelling in your ankles

Uncommon (may affect 1 to 10 in 1,000 people):
- mood changes (with short-term use)
- dizziness
- tingling in the hands or feet
- diarrhoea
- vomiting
- muscle ache or weakness in the legs

Not known: frequency cannot be estimated from the available data
- idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms and ringing or buzzing in one or both ears).
- blood tests may show anaemia (low red cell counts), low counts in white cells or platelets
- allergic reactions (may include symptoms of rash, itching, wheals)
- changes in blood lipids (cholesterol) or blood sugar
- paralysis
- seizure
- altered vision
- pounding heartbeats
- changes in ECG (QT prolongation)
- blood clots in lungs
- high or low blood pressure
- jaundice
- fracture of the spine
- thinning of bone
- difficulty passing urine
- fever
- chills
- inflammation of lungs or lung disease

Special notes:
Your response to treatment should be monitored by measuring testosterone blood concentrations 28 days after each injection and before each re-administration of Staladex and additionally on the basis of other laboratory tests.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk or search for MHRA Yellow card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Staladex

Do not use this medicine after the expiry date which is stated on the container and the outer packaging. The pre-filled syringe must be used immediately after opening the sterile pouch.
Do not store above 30°C. Store the pre-filled syringe in the unopened original package. Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Staladex contains:
The active substance is leuprorelin acetate.
The implant contains: 10.72 mg leuprorelin (as leuprorelin acetate 11.25 mg).
The other ingredients are polylactic acid and poly(D,L-lactide-co-glycolide) (1:1).

What Staladex looks like and contents of the pack
Plastic pre-filled syringe (with depot chamber) with stainless steel plunger and needle. The pre-filled syringe is packaged together with a desiccant in a sealed sterile plastic/aluminium foil laminate pouch. Packs of 1 pre-filled syringe containing 1 implant, 2 pre-filled syringes each containing 1 implant, 4 pre-filled syringes each containing 1 implant or bundle packs of 2 (2x1) or 4 (2x2 or 4x1) pre-filled syringes each containing 1 implant for subcutaneous injection.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Amdeepcha Limited
85 Yarmouth Road
Blofield
Norwich
Norfolk NR13 4LQ
United Kingdom

Manufacturer
AMW GmbH
Birkerfeld 11
83627 Warngau
Germany

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