

New Zealand Consumer Medicine Information

LEUPRORELIN SANDOZ

Leuprorelin acetate 3.6 mg, implant in pre-filled syringe [monthly]
Leuprorelin acetate 5 mg, implant in pre-filled syringe [3 monthly]

What is in this leaflet

Please read this leaflet carefully before you start using Leuprorelin Sandoz.

This leaflet answers some common questions about Leuprorelin Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Leuprorelin Sandoz against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Leuprorelin Sandoz is used for

The active substance of Leuprorelin Sandoz (leuprorelin acetate) belongs to the group of inhibitors of certain sex hormones.

Leuprorelin Sandoz acts on the pituitary gland, briefly stimulating then curbing production of the hormones that control the production of the sex hormones in the testes. This means that the concentrations of the sex hormones subsequently fall and, with continued administration, remain at this level. After discontinuing Leuprorelin Sandoz the concentrations of the pituitary and sex hormones return again to the normal range.

Leuprorelin Sandoz is used for symptomatic treatment of advanced hormone-dependent tumours of the prostate (prostate carcinoma).

Your doctor may have prescribed Leuprorelin Sandoz for another reason. Ask your doctor if you have any questions about why Leuprorelin Sandoz has been prescribed for you.

This medicine is available only with a doctor's prescription.

Leuprorelin Sandoz is not addictive.

Before you use Leuprorelin Sandoz

When you must not use it

Do not use Leuprorelin Sandoz if:

- you are **allergic** to leuprorelin or the other ingredient in this medicine; polylactic acid.
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- if you are allergic to substances similar to leuporelin, such as goserelin or buserelin.
- if your cancer is not effected by hormones.
- if you are a woman or a child.

If you are not sure whether you should start using Leuporelin Sandoz, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you have high blood pressure. In this case your doctor will monitor you carefully.
- you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Leuporelin Sandoz.
- both your testes have been surgically removed. In this case Leuporelin Sandoz does not produce any further fall in the blood concentration of the male sex hormone.
- you already have nervous system symptoms (pressure on the spinal cord, metastases in the spinal column) or discomfort when urinating due to displacement of the urinary tract. You should tell your doctor this without delay: he/she will monitor you particularly closely in the first weeks, if possible in hospital.
- there is a risk of you developing osteoporosis e.g. have a family history of osteoporosis, have a low calcium intake, are immobile. Your doctor will give you an additional medicine when possible, to prevent bone loss.
- you have diabetes. In this case your doctor will monitor you very closely.

If you have not told your doctor about any of the above, tell them before you start using Leuporelin Sandoz.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Leuporelin Sandoz.

Leuporelin Sandoz 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 drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

These medicines may be affected by Leuporelin Sandoz, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Leuporelin Sandoz.

How to use Leuporelin Sandoz

Having Leuporelin Sandoz

- Leuporelin Sandoz will be given as an injection under the skin (subcutaneous) in the stomach area.

- The site of the injection will be cleaned.
- A local anaesthetic may then be given to ease the pain of the implant injection.

Blood tests

Your doctor will need to give you regular blood tests to check whether this medicine is working. After 3 months of treatment your doctor usually clarifies whether your prostate cancer is treatable with Leuprorelin Sandoz. He/she must therefore check the prostate specific antigen (PSA) and testosterone levels.

How much to have

For monthly treatment:

The recommended dose is 1 implant with 3.6mg leuprorelin every month.

- The injection would normally be given by a doctor or a nurse.
- Follow your doctor's advice on when you should have Leuprorelin Sandoz and the time between each injection.
- Leuprorelin Sandoz injection will be given to you every month. If the next injection is postponed in exceptional cases for up to 2 weeks, the therapeutic effect is usually not impaired.
- The content of one pre-filled syringe is injected.
- The syringe contains one implant to give a dose of 3.6 mg of leuprorelin.

For 3 monthly treatment:

The recommended dose is 1 implant with 5 mg leuprorelin every 3 months of Leuprorelin Sandoz.

- The injection would normally be given by a doctor or a nurse.
- Follow your doctor's advice on when you should have Leuprorelin Sandoz and the time between each injection.
- Leuprorelin Sandoz injection will be given to you every 3 months. If the next injection is postponed in exceptional cases for up to 4 weeks, the therapeutic effect is usually not impaired.
- The content of one pre-filled syringe is injected.
- The syringe contains one implant to give a dose of 5 mg of leuprorelin.

How long to use it

To be decided by your attending doctor. Treatment should be continued, even if the cancer related symptoms have subsided or the cancer has improved.

Prostate cancer can be treated with this medicine for some years. Therefore, if it is effective and you can tolerate it, you can use it continuously. Your doctor will do tests at regular intervals to evaluate the therapy, particularly if symptoms recur such as:

- pain
- difficulty urinating
- weakness in the legs

If you forget to use it

Talk to your doctor if you think that your Leuprorelin Sandoz dose has been forgotten.

While you are using Leuprorelin Sandoz

Things you must do

Tell your doctor if symptoms of the disease reappear (such as pain, difficult urination or weakness in the legs) after prolonged use of Leuprorelin Sandoz. In this case your doctor will check the success of the treatment regularly by clinical examinations (digital rectal examination of the prostate, imaging examinations) and by checking blood values (phosphatases and prostate specific antigen (PSA) and the male sex hormone (testosterone)).

There have been reports of depression in patients taking Leuprorelin Sandoz which may be severe. If you are taking Leuprorelin Sandoz and develop a depressed mood, inform your doctor.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Leuprorelin Sandoz.

Be sure to keep all your doctor's appointments so your progress can be checked.

Things you must not do

Do not give Leuprorelin Sandoz to anyone else, even if they have the same condition as you.

If treatment is stopped without your doctor's approval, symptoms associated with your disease can worsen. Therapy should therefore not be discontinued prematurely without your doctor's permission.

Things to be careful of

This medicine and also the tumour disease may cause **tiredness**. This is more likely to occur with alcohol use.

Therefore, **do not drive or operate machinery** without your doctor's permission **if this applies** to you.

In case of overdose

It is unlikely that your doctor or nurse will give you too much medicine.

If a larger amount is accidentally given, your doctor will monitor you and, if necessary give you appropriate treatment.

If you experience any side effects after taking Leuprorelin Sandoz immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Leuprorelin Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Contact your doctor immediately or go to accident and emergency at your nearest hospital if you experience the following severe side effects:

- **Allergic reactions** (anaphylactic reactions). The symptoms can include sudden onset of:
 - Feeling hot, rash, itching or hives on the skin and/or mucosa.
 - Swelling of the face, lips or tongue or other parts of the body.
 - Shortness of breath, wheezing or trouble breathing.
 - Fall in blood pressure, accelerated heartbeat, convulsions, and in the severest cases, life-threatening failure of the cardiovascular system.
- **Swelling and pain in a part of the body** due to a blood clot within a vein.
- **Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin and discolouration** due to a blood clot in the lungs.

These side effects are rare (may affect up to 1 in 1,000 people).

There is routinely an initial short-term increase in the male sex hormone (testosterone) in the blood. As a result the following disease-related symptoms may be temporarily aggravated:

- Occurrence or increase in bone pain
- Difficult urination owing to the urinary tract being displaced
- Pressure on the spinal cord
- Muscle weakness in the legs
- Swellings due to fluid in the tissues being prevented from flowing away (lymphatic oedema)

This increase in symptoms normally regresses without Leuprorelin Sandoz having to be discontinued.

When beginning the treatment, administration should be considered of a suitable male sex hormone antagonist (anti-androgen), to lessen the possible consequences of the initial increase in the male sex hormone.

Decrease in the sex hormone testosterone, as occurs after removal of the testicles or with treatment with medicines to inhibit the sex hormones (such as Leuprorelin Sandoz), can cause reduction in bone density with an increased risk of bone fractures. The reduction in bone density after removal of the testicles is however more marked than after administration of Leuprorelin Sandoz. Your doctor will consider additional administration of a medicinal product to regulate calcium metabolism (known as a bisphosphonate).

In the course of the treatment the male sex hormone falls to a very low level. As a result, in certain patients the following side effects appear:

Very common: may affect more than 1 in 10 people

- hot flushes
- increased sweating
- bone pain
- reduction in or loss of sexual desire and potency
- testicular size reduction (Uncommon for 3.6mg strength)
- weight gain (Uncommon for 3.6mg strength)
- local skin reactions such as reddening or induration, pain, swelling and itching at the injection site, which normally subside even when treatment continues; in isolated cases an abscess has appeared (Very rare for 3.6mg strength)

Common: may affect up to 1 in 10 people

- male breast enlargement (Uncommon for 3.6mg strength)
- decreased appetite (Uncommon for 3.6mg strength)
- increased appetite
- depression, mood changes
- sleep disturbances
- headache (Uncommon for 3.6mg strength)
- abnormal sensations, such as feelings of tingling and/or numbness
- nausea/vomiting (Very rare for 3.6mg strength)
- joint or back pain (Very rare for 3.6mg strength)

- muscle weakness (Very rare for 3.6mg strength)
- pain in the area between anus and genitals (5mg strength only)
- upper abdominal pain (5mg strength only)
- increased need to urinate at night
- excessive frequent need to urinate at daytime
- difficulty and pain when passing urine
- tiredness (Very rare for 3.6mg strength)
- swelling of the ankles, feet or fingers (peripheral oedema) (Very rare for 3.6mg strength)
- weight loss (Uncommon for 3.6mg strength)
- general weakness (Very rare for 3.6mg strength)
- increase in the blood levels of liver enzymes (ALT, AST, gamma-GT) and other enzymes (LDH, alkaline phosphatase) (Uncommon for 3.6mg strength)

Uncommon: may affect up to 1 in 100 people

- general allergic reactions such as fever, itching, increase in eosinophil blood cells, skin rash (Very rare for 3.6mg strength)
- diarrhoea
- dry skin or mucosa
- testicular pain
- inability to empty the full bladder spontaneously
- increased sweating at night
- lowered or increased blood sugar levels (Rare for 5mg strength)
- dizziness (Rare for 5mg strength)
- lowered or increased blood pressure (Rare for 5mg strength)
- hair loss (Rare for 5mg strength)

Rare: may affect up to 1 in 1,000 people

- passing taste changes (Very rare for 3.6mg strength)

Very rare, may affect up to 1 in 10,000 people

- As with other medicines in this class of substances: pituitary infarction after the first administration in patients with a pituitary tumour

Not known (**frequency cannot be estimated from the available data**)

- non-infectious lung disease (pneumonia) (reported mainly from Japan)
- in isolated cases an abscess has appeared at the injection site
- changes in ECG (QT prolongation)
- convulsion
- loss in bone density

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Leuprorelin Sandoz

Storage

Keep this medicine out of the sight and reach of children

Do not store above 30 °C.

Do not use this medicine after the expiry date, which is stated on the outer carton as well as on the sterile bag and the label of the syringe after EXP. The expiry date refers to the last day of that month.

Disposal

Return any unused medicine or any medicine past its expiry date to your pharmacist for disposal.

Product description

What it looks like

Pre-filled plastic syringe of polycarbonate with a plunger of acrylonitril-butadien-styrene copolymer and a needle sealed in a bag of polyethylene terephthalate/aluminium/PE composite foil.

Packs containing:

- 1 x 1 implant with 3.6 mg or 5 mg leuprorelin (as leuprorelin acetate)
- 2 x 1 implant with 3.6 mg or 5 mg leuprorelin (as leuprorelin acetate)
- 3 x 1 implant with 3.6 mg or 5 mg leuprorelin (as leuprorelin acetate)
- 5 x 1 implant with 3.6 mg or 5 mg leuprorelin (as leuprorelin acetate)

Not all pack sizes may be marketed.

Ingredients

The active substance is leuprorelin (as leuprorelin acetate).

1 implant contains 3.6 mg or 5 mg leuprorelin (as leuprorelin acetate).

The other ingredient is Poly(lactic-co-glycolic acid) 1:1 (3.6mg strength) or polylactic acid 95mg strength).

Sponsor Details

Leuprorelin Sandoz is supplied in New Zealand by:

Novartis New Zealand Limited
PO Box 99102
Newmarket
AUCKLAND 1149

Telephone: 0800 354 335

Date of Preparation

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