# ACKAGE LEAFLET: INFORMATION FOR THE USER

# Leupro-Sandoz 3-Month Depot

**Leuprorelin**

**Read all of this leaflet carefully before the use of this medicine is started.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**


## 1. WHAT LEUPRO-SANDOZ 3-MONTH DEPOT IS AND WHAT IT IS USED FOR

Leupro-Sandoz 3-Month Depot is used to **relieve disease-related symptoms in men** with:
**advanced prostate cancer**, which is influenced by hormones

Leupro-Sandoz 3-Month Depot acts on the pituitary gland, which regulates production of the male sex hormone testosterone in the testes. After a short-term increase, it reduces the testosterone level which then remains stable throughout the treatment.

If both your testes have been removed surgically Leupro-Sandoz 3-Month Depot does not further reduce the testosterone level in the blood.

Testosterone reduction is needed if cancer is influenced by hormones, as it reduces cancer growth in the prostate. If leuprorelin treatment is stopped, all hormone levels will gradually increase again to the normal range.

## 2. BEFORE YOU USE LEUPRO-SANDOZ 3-MONTH DEPOT

**Do not use Leupro-Sandoz 3-Month Depot**
- if you are **hypersensitive** (allergic) **to**
  - leuprorelin,
  - substances similar to leuprorelin, such as goserelin or buserelin
  - poly(lactic-co-glycolic acid).
- if your **cancer is not effected by hormones**.
- if you are a woman or a child.

**Take special care with Leupro-Sandoz 3-Month Depot**
- if any of the following apply to you, **inform your doctor** about this before beginning treatment. He will monitor you during the first weeks of treatment and possibly hospitalize you.
  - pressure effects on the **spinal cord**
  - **metastases** spread in the spinal column or brain
  - difficulty or pain when **urinating**

- if the following disease related complaints occur or increase during treatment:
  - bone pain
  - difficulty or pain when urinating
  - pressure effects on the spinal cord
  - weakness or tingling sensation in the legs
  - lymph swelling due to reduced drainage of tissue water

These conditions may occur at the beginning of treatment due to a short-term testosterone increase. They usually subside spontaneously without forcing Leupro-Sandoz 3-Month Depot to be discontinued. Your doctor may consider prescribing a suitable medicine to lessen these possible conditions.

- if you have **diabetes** or if you suffer from **heart problems, inform your doctor**."

**DE (RMS)**
Blue Box Information: Information on doping

**Taking other medicines**
Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

**No interactions** with other medicines **are known**.

**Children**
Leupro-Sandoz 3-Month Depot is only intended for adult patients.

**Pregnancy and breast-feeding**
Leupro-Sandoz 3-Month Depot is only intended for male patients.

**Driving and using machines**
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 doctors' permission **if this applies** to you.

## 3. HOW TO USE LEUPRO-SANDOZ 3-MONTH DEPOT

Leupro-Sandoz 3-Month Depot treatment will be performed by a doctor experienced in tumour therapy.

The **usual dose is**: 1 implant with 5 mg leuprorelin once every three months.

Only your doctor will inject the implant under your abdominal skin. After the 2nd application, use may be postponed in exceptional cases for up to 4 weeks. The therapeutic effect in most patients is usually not impaired.

After 3 months of treatment your doctor usually clarifies whether your prostate cancer is treatable with Leupro-Sandoz 3-Month Depot. He must therefore check the prostate specific antigen (PSA) and testosterone levels.

**Duration of use**
To be decided by your attending doctor.

Prostate cancer can be treated with Leupro-Sandoz 3-Month Depot 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 Leupro-Sandoz 3-Month Depot is given more often than it should**
Overdoses are not expected, as the injection is usually given by your doctor.
If a larger amount is accidentally given, your doctor will monitor you and, if necessary use additional treatment.

**If you forget to use Leupro-Sandoz 3-Month Depot**
Please talk to your doctor if you think that your Leupro-Sandoz 3-Month Depot dose has been forgotten.

**If you stop using Leupro-Sandoz 3-Month Depot**
If treatment is stopped without your doctors' approval, symptoms associated with your disease can worsen.
Therapy should therefore not be discontinued prematurely without your doctors' permission.

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

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Leupro-Sandoz 3-Month Depot can cause side effects, although not everybody gets them.

**Side effects can occur with the following frequencies:**

**Very common**, affects more than 1 user in 10
- hot flushes with sweating bouts
- reduced sexual desire and potency
- increased sweating

**Uncommon**, affects 1 to 10 users in 1,000
- clotting within a vein causing swelling and pain
- blood clot in the lungs causing difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin and discolouration
- breast swelling
- decreased appetite
- lowered or increased blood sugar levels
- depressed mood
- headache
- dizziness
- lowered or increased blood pressure
- difficult breathing
- diarrhoea
- hair loss
- testicular size reduction
- weight gain
- increase in the blood levels of liver enzymes (ALT, AST, gamma-GT) and other enzymes (LDH, alkaline and acid phosphatase)

Very rare, affects less than 1 user in 10,000
- general allergic reactions (fever, skin rash, itching, serious allergic reactions which cause difficulty breathing or dizziness)
- passing taste changes
- nausea/vomiting
- joint and muscle complaints
- oedema
- tiredness
- local skin reactions, e.g. reddening at the injection site, which usually subsides even when treatment continues
- thrombosis of the central retinal artery
- pituitary gland dysfunction
- death of an area of tissue in the pituitary gland in patients with tumours of the pituitary gland

Treatment with Leupro-Sandoz 3-Month Depot may lead to bone loss, osteoporosis and a higher risk of bone fractures. Patients at risk should discuss prevention measures with the attending doctor.

If any of the **side effects** gets serious, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist**.

## 5. HOW TO STORE LEUPRO-SANDOZ 3-MONTH DEPOT

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use the 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.

## 6. FURTHER INFORMATION

**What Leupro-Sandoz 3-Month Depot contains**
The **active substance** is: **leuprorelin (as acetate)**
1 implant contains 5 mg leuprorelin (as acetate)
The other ingredient is: polylactic acid

**What Leupro-Sandoz 3-Month Depot looks like and contents of the pack**
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. The bag also contains a sodium aluminium silicate desiccant.

Packs containing:
1 pre-filled syringe with 1 implant
2 pre-filled syringes with 1 implant each
3 pre-filled syringes with 1 implant each
5 pre-filled syringes with 1 implant each

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Sandoz Pharmaceuticals GmbH
Holzkirchen, Germany

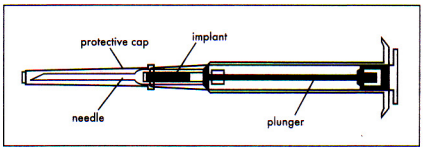
**Manufacturer**
JENAHEXAL Pharma GmbH
Otto-Schott-Str. 15
07745 Jena, Germany

50022048
46035730

**This leaflet was last revised in November 2007.**

**The following information is intended for medical or healthcare professionals only**

**Directions for use**

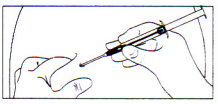



1. Disinfect the injection site on the anterior abdominal wall below the navel line.

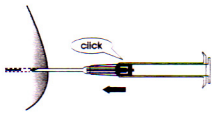
2. Remove the syringe from the sterile bag and check that the implant is visible in the repository. If necessary, view the syringe against a light or gently shake it.

3. Pull the syringe plunger **completely backwards to the stop position**. During this procedure it will click several times. Then remove the protective cap from the needle.
**Please note:** The plunger can be pushed forward to inject the implant only if it has been previously **pulled back completely to the stop position!**

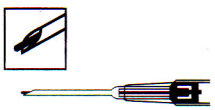

4. Hold the main body of the syringe with one hand. With the other hand pinch the patient's skin. Insert the whole needle at a slight angle, almost parallel to the skin with the needle opening facing upwards into the subcutaneous tissue of the anterior abdominal wall below the navel line.



5. Carefully pull the syringe approximately 1 cm backwards (puncture canal for the implant). To inject the implant into the puncture canal, push the plunger completely forwards until it snaps into place and you hear a click.




6. Withdraw the needle. To ensure that the implant has been injected correctly, check that the white tip of the plunger is visible at the tip of the needle.



**For dosing information please refer to section 3. "HOW TO USE Leupro-Sandoz 3-Month Depot?".**