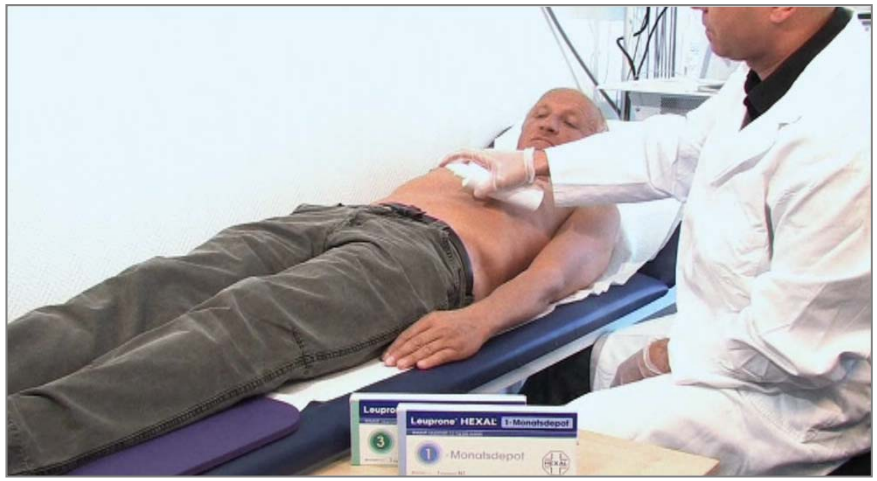
ROWEX

Leuprex 3 Administration Guide

Leuprorelin



Preparation

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

Single dose efficient for 3 months.

This guide is for Leuprex 3 administration only.
For Healthcare Professional use only.
Prescribing information and reference can be found on the last page.

Leuprex 3
5 mg Implant
Leuprorelin

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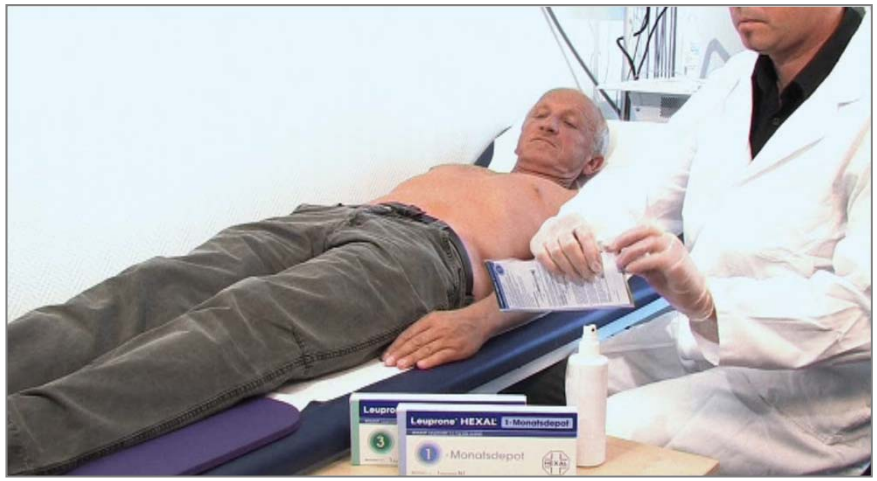
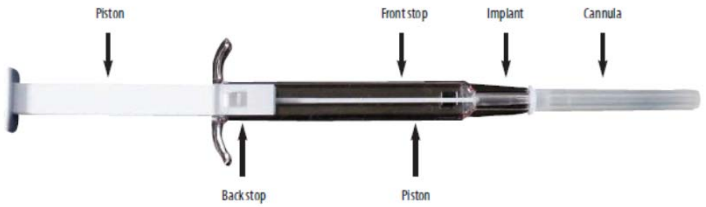
Leuprorelin



Preparation

- Remove the syringe from the sterile bag.



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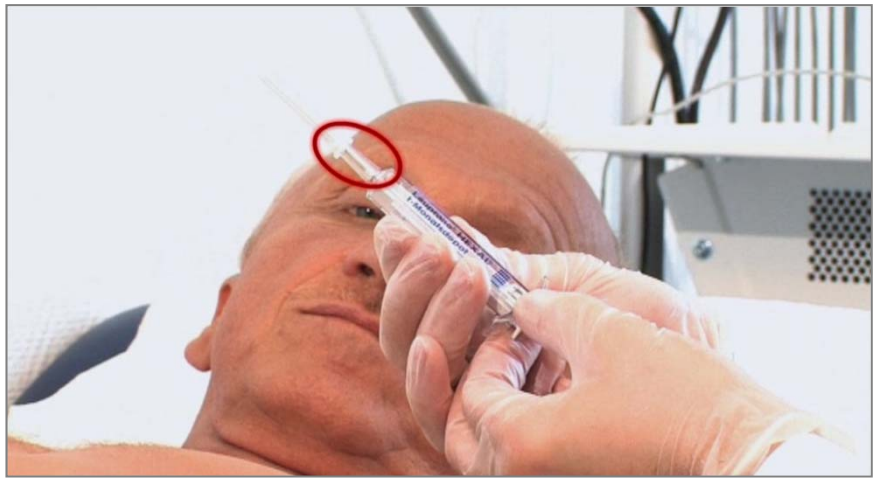

Preparation

- Check that the implant is visible in the repository. If necessary, view the syringe against a light or gently shake it.

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Preparation

- Pull the syringe plunger completely backwards to the stop position.
- During this procedure it will click several times.

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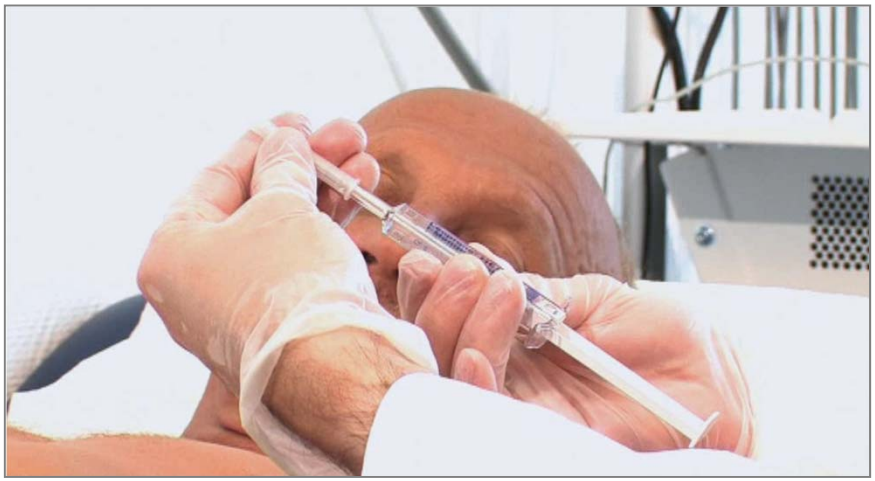

Preparation

- 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.

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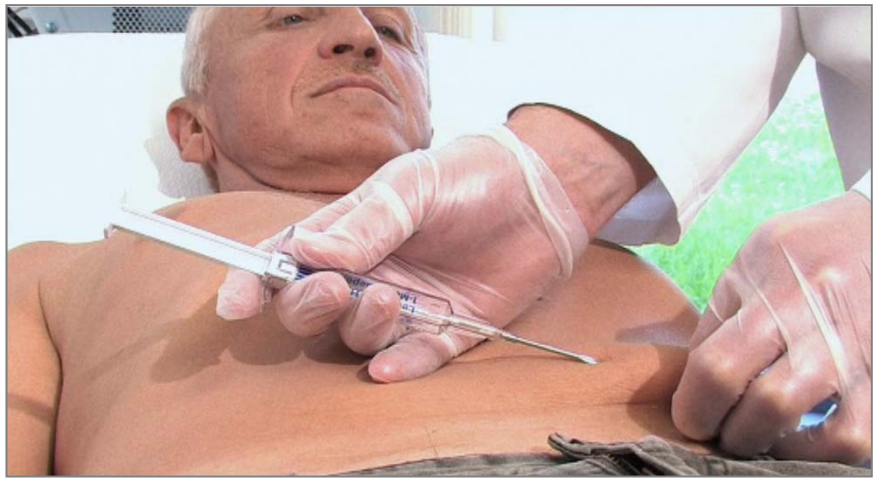

Insert needle

- Hold the main body of the syringe with one hand.
- With the other hand pinch the patient's skin.

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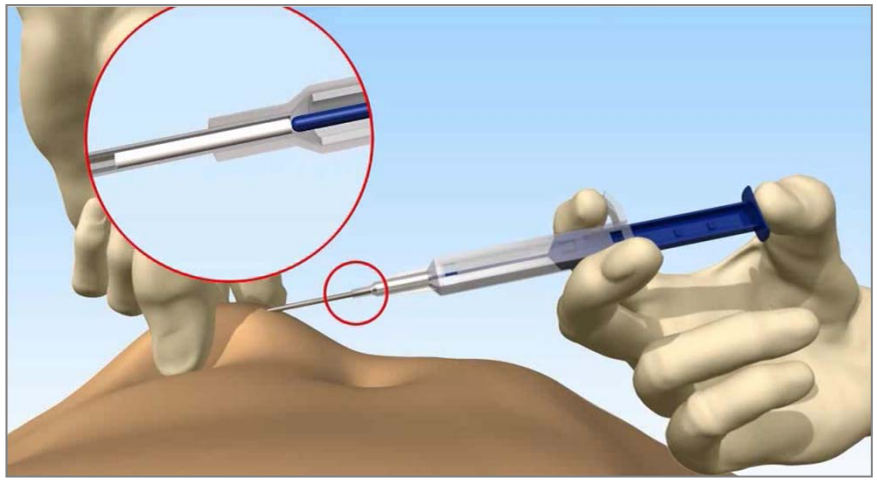

Insert needle

- 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.

Single dose efficient for 3 months.

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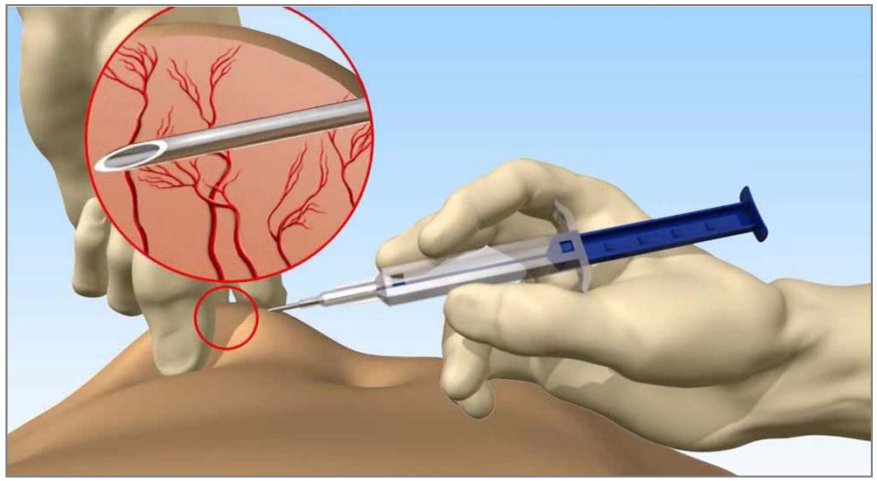

Insert needle

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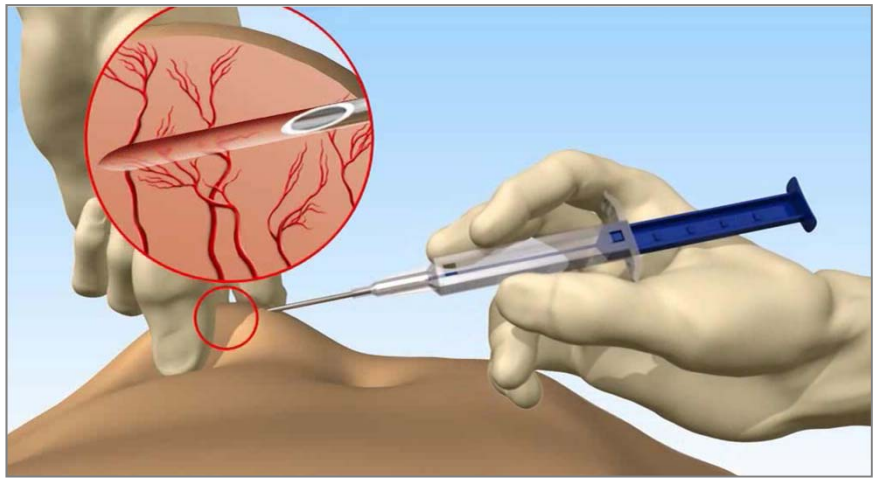

Puncture Canal

- Carefully pull the syringe approximately 1cm backwards (puncture canal for the implant).

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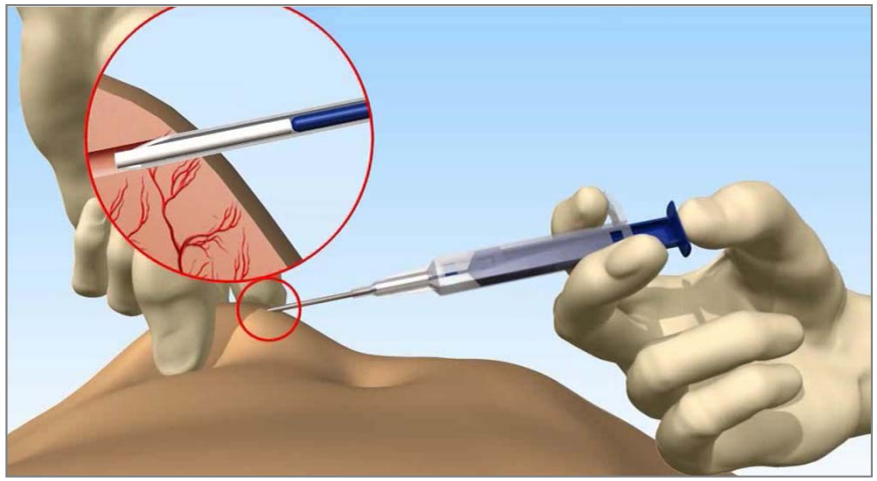

Injection implant depot

- To inject the implant into the puncture canal, push the plunger completely forwards until it snaps into place.

Single dose efficient for 3 months.

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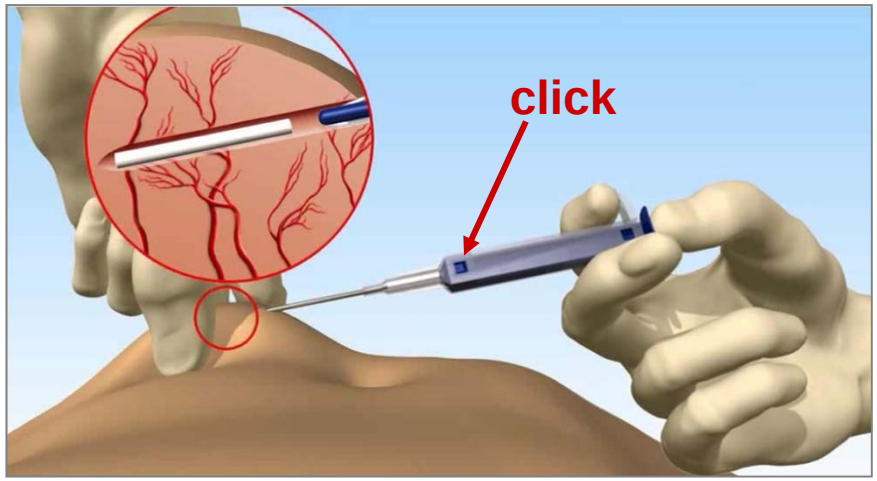

Injection implant depot

- To inject the implant into the puncture canal, push the plunger completely forwards until it snaps into place.
- You hear a click.

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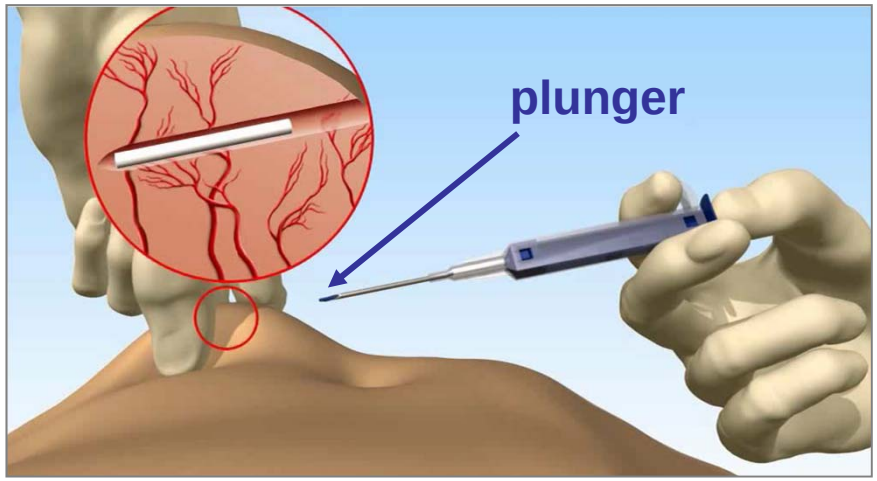

Withdraw needle

- To ensure that the implant has been injected correctly, check that the light blue tip of the plunger is visible at the tip of the needle.

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5 mg Implant
Leuprorelin

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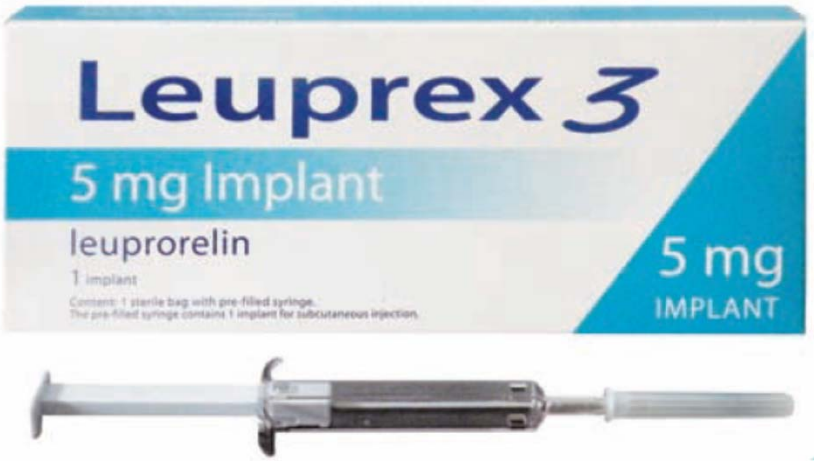
Leuprex 3 Because less is more

Leuprorelin

The 1st Leuprorelin implant

- Less active ingredient with comparable efficacy rates
- Good tolerability[1]
- Ready to use formulation
- Completely biodegradable
- Most cost-effective Leuprorelin[2]
- No need to refrigerate[3]



Reliable option to safe time and money.

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Leuprex 3 Prescribing information

Leuprorelin

Abbreviated Prescribing Information

Product Name: Leuprex 3, 5mg Implant. **Composition:** Each implant contains 5mg leuprorelin (as acetate). **Description:** Implant. Biodegradable white to slightly yellowish cylinder shaped stick (length 10mm) in a pre-filled syringe. **Indication(s):** Palliative treatment of patients with advanced hormone-dependent prostate carcinoma. **Dosage:** The 5mg leuprorelin implant is inserted subcutaneously into abdominal skin, using an aseptic technique once every 3 months. (Refer to SPC and PIL for directions). Monitor PSA levels and serum testosterone at regular intervals. **Contraindications:** Hypersensitivity to leuprorelin, other GnRH analogues or to polylactic acid. In cases where carcinomas are shown to be hormonally independent. After surgical castration, the implant does not cause further reduction in testosterone levels. In women and paediatric patients. **Warnings and Precautions for Use:** Leuprorelin causes a transient increase in the serum concentration of testosterone during the first week of treatment; this may be associated with a 'flare' or exacerbation of the tumour growth and can include worsening of symptoms or onset of new symptoms. These symptoms usually subside on continuation of therapy. To reduce risk of 'flare' an anti-androgen may be administered beginning 3 days prior to leuprorelin therapy and continue for the first 2-3 weeks of treatment. Close monitoring is required of patients with vertebral or cerebral metastases and/or those with a urinary tract obstruction as spinal cord compression and impaired renal function have been observed in isolated cases. Patients may experience metabolic changes and cardiovascular disorders. Patients at high risk for metabolic or cardiovascular diseases should be carefully assessed before treatment and adequately monitored during androgen deprivation therapy. Increased risk of incident depression (which may be severe). Inform patients accordingly and treat as appropriate if symptoms occur. **Interactions:** There are no known interactions with other agents. **Pregnancy and Lactation:** Not applicable.
Ability to Drive and Use Machinery: This medicinal product may alter reactivity to such an extent that the ability to drive or to operate machinery is impaired. This applies to a greater extent in combination with alcohol. **Undesirable Effects:** *Very common:* hot flushes, ostalgia, reduction in or loss of libido and sexual potency, testicular size reduction, increased diaphoresis, reactions at the injection site e.g. reddening, pain, oedema, itching which usually subsided even when treatment was continued, weight gain. *Common:* gynaecomastia, decreased appetite, sleep disorders, headache, paraesthesia, nausea, arthralgia or dorsalgia, myasthenia, perineal pain, upper abdominal pain, nocturia, dysuria, fatigue, peripheral oedema, generalised weakness, weight loss, increases in LDH, transaminases (ALT, AST), gamma-GT and alkaline phosphatase, which may also be a manifestation of the underlying disease. *Common in long term use, but uncommon in short term use*: mood disorders and depression.
Marketing Authorisation Holder: Rowex Ltd, Bantry, Co. Cork. **Marketing Authorisation Number:** PA 711/188/1.
Further information and SPC are available from: Rowex Ltd, Bantry, Co. Cork. Freephone: 1800 304 400 Fax: 027 50417. E-mail rowex@rowa-pharma.ie
Legal Category: Medicinal product subject to prescription which may not be renewed.
Date of Preparation: June 2013

1 Clinical study report 2001-33-IMP-8. Data on file (2006).
2 MIMS (2013).
3 Summary of product characteristics (2012).

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