

Leaflet	Leupromer® 7.5 (EXP)
Size	240 x 170 mm
Date	1401.09.05

Colors:
● PANTONE Strong Red U

240 mm

170 mm

Leupromer® 7.5
Leuprorelin acetate



powder and solvent for Extended-release
suspension for injection

Read all of this leaflet carefully before you starts using this medicine.

- 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. 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Leupromer is and what it is used for
2. Before you use Leupromer
3. How to use Leupromer
4. Possible side effects
5. How to store Leupromer

1. WHAT LEUPROMER IS AND WHAT IT IS USED FOR

Mechanism of Action

Causes suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone (male) and estrogen (female) levels.

Leupromercontains Leuprorelin, which is similar to a hormone called gonadotropin releasing hormone (GnRH analogue). It is a long acting formulation designed to slowly deliver 7.5mg of Leuprorelin over a 1-month period (four weeks). It acts by lowering the levels of the Sex hormone in the body.

Leupromeris used to treat locally advanced, hormone-dependent prostate cancer alone or during and following radiation therapy. It is also used to treat hormone-dependent prostate cancer which has spread to other parts of the body (metastatic cancer).

2. BEFORE YOU USE LEUPROMER

Do not use Leupromer

If you are allergic (hypersensitive) to Leuprorelin, gonadotropin releasing-hormone (GnRH), other GnRH analogues or any of the excipients of Leupromer.

Take special care with Leupromer

- At the beginning of the treatment there will be an increased amount of sex hormone in your body. This may cause the symptoms of the cancer to get worse. Contact your doctor if this happens. The doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse.
- During the first weeks of treatment, Leupromer may, as with other GnRH analogues, in isolated cases, cause the spinal cord to compress or the urethra (where you pass urine) to block. You will be monitored by your doctor and given treatment for these conditions if they occur.
- After surgical castration Leuprorelin does not induce any further decrease in serum testosterone levels and therefore should not be used after orchiectomy.
- Diagnostic tests of pituitary gonadal function conducted during treatment or after discontinuation of therapy with Leupromer may be misleading.
- Treatment with Leupromer may, as with other GnRH analogues, lead to bone loss, osteoporosis and a higher risk of bone fractures, especially 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).
- If you have diabetes or if you suffer from heart or vascular problems or depression, inform your doctor.
- If you have an enlargement (benign tumor) of the pituitary gland that you were unaware of, this may be discovered during treatment with Leupromer.

Symptoms include sudden headache, vomiting, problems with eye sight and paralysis of the eyes.

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

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Leupromer is not for use in pregnancy and breast-feeding women.

Driving and using machines

Even if used as directed Leupromer may change 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. These are possible side effects of treatment or from the underlying disease.

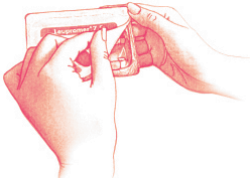
If you experience any of these side affects you should not drive or use machines.

3. How to use Leupromer

Allow the product to come to room temperature by removing from the refrigerator approximately 30 minutes prior to use.

Please prepare the patient for injection first, followed by the preparation of the product, using the instructions below. If the product is not prepared using the proper technique, it should not be administered as lack of clinical efficacy may occur due to incorrect reconstitution of the product.

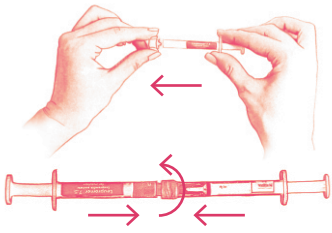
- **Step 1:** Open tray (tear off the foil from the corner which can be recognized by a small bubble) and empty the content onto a clean field (tray containing prefilled Syringe A and prefilled Syringe B, Needle and two Vario NeedlePad (Lidocaine anesthetic pad). Discard the desiccant pouches.



- **Step 2:** Clean the skin with one Vario NeedlePad (Lidocaine anesthetic pad), Start at the proposed site then wipe in a circular motion, moving outward with each circle to prepare an area 2-3 inches in diameter around the injection site and hold it for 30 seconds.



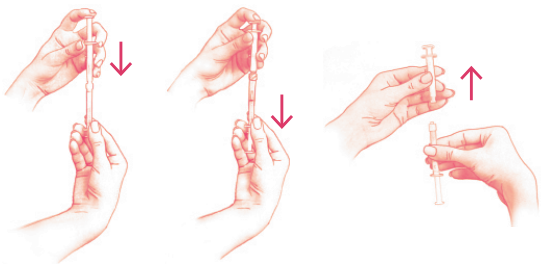
- **Step 3:** Gently open plugs of syringes. Join the two syringes together by twisting Syringe B onto Syringe A until secure, do not over tighten.



- **Step 4:** Thoroughly mix the product by gently pushing the contents of both syringes back and forth between syringes (60 times in total, which takes approximately 60 seconds) in a horizontal position to obtain a homogenous, viscous solution. Do not bend the syringe system (please note that this may cause leakage as you may partially unscrew the syringes).



- **Step 5:** Hold the syringes vertically with Syringe A on the bottom. The syringes should remain securely coupled. Draw the entire mixed product into Syringe A by pushing down the Syringe B plunger and slightly withdrawing the Syringe A plunger.



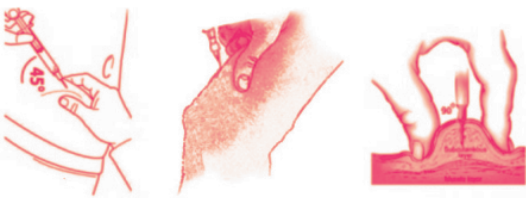
- **Step 6:** Twist off Syringe B while continuing to push down on the Syringe B plunger.

Ensure that no product leaks out as the needle will then not secure properly when attached.

Please note: one large or a few small air bubbles may remain in the formulation this is acceptable.

Please do not purge the air bubbles from Syringe B at this stage as product may be lost!

- **Step 7:** Hold Syringe A upright. Open pack of the safety needle by peeling back paper tab and take out safety needle. Secure the needle to Syringe A by holding the syringe and twisting the needle clockwise to fully seat the needle and Pull off the protective needle cap. Do not over tighten.
- **Step 8:** Lift up a fold of skin of upper arms or abdomen between thumb and forefinger. Insert needle at a 45-degree angle then press down on the plunger and slowly inject the contents of the syringe. Hold the syringe in place for 30 seconds after injecting then remove Syringe and put needle cap, immediately dispose of the needle and syringe in an approved sharps container.



- **Step 9:** Clean the injection site with second Vario NeedlePad (Lidocaine anesthetic pad) and hold the pad for 30 seconds.

4. POSSIBLE SIDE EFFECTS

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

As seen following treatment with other GnRH agonist therapies or after surgical castration, the most commonly observed adverse events related to Leuprorelin treatment were due to its expected pharmacological effects. These effects included hot flushes (50%), impotence (4%), and decreased libido (3%).Increased lymphocyte count has been reported with patients undergoing GnRH analogue treatment.

With the exception of immuno-allergic reactions and injection site reactions, all adverse events are known to be related to changed testosterone levels. As with other GnRH agonist, hypersensitivity and allergic (anaphylactic) reactions have been reported with Leuprorelin.

Very common side effects affecting more than 1 in 10 patients:

- Hot flushes
- Weakness
- Excessive sweating
- Back pain
- Pins and needles sensation in the legs

Common side effects affecting more than 1 in 100 patients:

- Nausea
- Tiredness, redness or pain at the injection site
- Dizziness
- Headache
- loss of libido

Uncommon side effects affecting more than 1 in 1000 patients:

- Ringing in the ears
- Pain in abdomen, constipation, diarrhea, vomiting
- Drowsiness, shaking, sleepiness, pain
- Difficulty in breathing
- Acne, hair loss, itching, rash
- High blood pressure
- Loss of appetite

5. HOW TO STORE LEUPROMER

Store in a refrigerator (2°C - 8°C).

Store in the original package in order to protect from moisture.

Keep out of the sight and reach of children.

170 mm