Lutropin alfa (rch) Recombinant human luteinsing hormone



What is Luveris used for?

Drua

CLN 034

Luveris is a medicine containing lutropin alfa, a recombinant luteinizing hormone (LH) which is similar to the hormone found naturally in humans, but is man made. It belongs to the family of hormones called gonadotrophins, which are involved in the normal control of reproduction.

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Luveris is recommended for the treatment of women who have been shown to produce very low levels of some of the hormones involved in the natural reproductive cycle. The medicine is used together with another hormone called FSH (follicle stimulatinghormone) to bring about the development of follicles, which are in the ovary and the structures where eggs grow and mature. It is often followed by treatment with a single dose of human chorionic gonadotrophins (hCG), which leads to the release of the egg from the follicle (ovulation).

Compared to natural conception, there is a risk of multiple pregnancy and births. However, this risk is minimised by using the recommended dose and time of injections. Luveris is not addictive.

This medication does not interfere with your ability to drive a car or operate machinery. This medicine is available only on a doctor's prescription.

DO NOT use Luveris if:

- You have a history of allergy to gonadotrophins or to any of the ingredients listed at the end of this leaflet.
- You are pregnant
- You are breastfeeding
- Your ovaries are enlarged
- You have an ovarian cyst that is not due to polycystic ovaries
- You have unexplained vaginal bleeding
- You have cancer of the ovaries, uterus or breast
- You have a brain tumour
- Do not take Luveris after the expiry date on the package has been passed.
- Do not take Luveris if the packing is torn or shows signs of tampering.
- If your medicine has expired or is damaged, return it to your pharmacist/ clinic for disposal

Before you use Luveris

TELL YOUR DOCTOR if you have any allergies to:

- Any other medicines
- Any other substances such as foods, preservatives or dyes

TELL YOUR DOCTOR if you have or have had any medical conditions, especially the following:

- Premature menopause
- Uncontrolled thyroid or adrenal gland disease
- High prolactin levels in the blood
- Cancer of the pituitary gland or hypothalamus
- Fibroid tumours in your uterus which would make pregnancy impossible
- If you have been through menopause
- Kidney disease
- Liver disease

Treatment with Luveris may increase your risk

of developing a condition known as ovarian

hyperstimulation syndrome (OHSS). This is when

the ovaries over react to the hormone treatment and develop too many follicles.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by use of ultrasound and blood test to measure oestrogen levels. This will help to indicate if you are likely to develop OHSS.

TELL YOUR DOCTOR

- if you plan to have surgery
- if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Luveris 75 IU

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How is Luveris given?

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Luveris is given as a course of daily injections, often at the same time as FSH medicine (Gonal F) Luveris should not be given in the same injection with other drugs except Gonal F.

Follow all directions given to you by your doctor or clinic nurse carefully. They may differ from the information contained in this leaflet.

How much is injected?

It is recommended that your treatment with Luveris starts at 75iu daily, but your doctor may adjust your dose depending on your individual response to treatment. You will be told by your doctor or clinic nurse exactly when to give the injection. Each vial is for single use only.

How to inject

Luveris is given as a subcutaneous injection (under your skin) in the lower abdominal area or thigh each day at approximately the same time.

Luveris can be injected by yourself or your partner. Alternatively it can be injected at the clinic by a nurse. If you decide to do your own injections the clinic nurse will teach you the injection technique.

Do not self-inject until you are sure of how to do it.

Do not inject into areas in which you feel lumps, firm knots, depressions, pain or discolouration.

If you forget to inject Luveris

If you forget an injection or are not sure what to do, contact your doctor or clinic nurse for advice.

Side effects

TELL YOUR DOCTOR or clinic nurse if you do not feel well while taking Luveris.

All medicines have side effects. Sometimes they are more serious, most of the time they are not.

If you think you have side effects do not stop taking Luveris without first talking to your doctor. **TELL YOUR DOCTOR** if you notice any of the following and they worry you:

- Headache
- Abdominal pain
- Breast pain
- Nausea
- Sleepiness
- Ovarian cysts
- Bruising, pain, redness, itching or swelling at the site of injection

TELL YOUR DOCTOR immediately if you

experience any of the following:

- Bleeding
- Inflammation, swelling or pain in your legs
- Severe pelvic pain, nausea, vomiting and weight gain, these are early signs of OHSS

If any of the following happen, stop using Luveris and tell your doctor immediately or go to the accident ϑ emergency at your nearest hospital.

- Swelling of the face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or difficulty breathing
- Severe skin rash, itching or hives

Other side effects not listed may happen in some patients. Tell your doctor or clinic nurse if you notice anything that is making you feel unwell.

Storage

Before Luveris is mixed with the solvent it should be kept in a cool dry place below 25°C in its original packaging.

- Once Luveris is mixed with the solvent it should be injected immediately. Any left over must be discarded.
- Do not use the dissolved solution if it has particles in it or is not clear
- DO NOT LEAVE IN THE CAR
- Keep this medicine where children cannot reach it.

Disposal

- If you are self injecting you should dispose of all sharps in the sharps container provided
- If you have any Luveris that has expired or is left over return it to your clinic or pharmacy.