

## **Patient Package Insert according to Pharmacists' Regulations (Preparations) 1986**

This medicine can be sold with a doctor's prescription only

# **Rekovele 36/72**

## **Solution for subcutaneous injection**

### **Composition:**

Each **Rekovele 36** multi-dose pen contains 36 mcg of follitropin delta

Each **Rekovele 72** multi-dose pen contains 72 mcg of follitropin delta

**Inactive ingredients-** see section 6 "additional information".

**Read this entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about the medicine. 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 might harm them, even if you think that their illness is similar to yours.

This medicine is intended for adult women over 18 years of age.

### **1. What is the medicine intended for?**

Rekovele is a medicine that contains follitropin delta. This is a follicle-stimulating hormone and belongs to the family of hormones called gonadotropins. Gonadotropins are involved in reproduction and fertility.

Rekovele is intended for the treatment of women undergoing fertility treatments such as in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) micromanipulation. Rekovele stimulates the production of multiple follicles in the ovaries from which the eggs are collected to be fertilized in the laboratory.

**Therapeutic group:** Gonadotropins

### **2. Before Using the Medicine**

Before starting treatment, you and your partner in the fertility process must be checked by a doctor who specializes in the treatment of fertility problems.

#### **Do not use the medicine if**

- you are hypersensitive (allergic) to follitropin delta or to any of the inactive ingredients of this medicine (see section 6).
- you have a tumor of the uterus, ovaries, breasts, pituitary gland or hypothalamus.
- you have enlarged ovaries or cysts on your ovaries (unless caused by polycystic ovarian disease).
- you suffer from vaginal bleeding without any known cause.
- you have reached menopause at an early age.
- you have malformations of the reproductive organs that make a normal pregnancy impossible.
- you have fibroids of the uterus (benign tumors) that make a normal pregnancy impossible.

### **Special warnings regarding the use of this medicine**

#### **Ovarian hyperstimulation syndrome**

Medicines belonging to the gonadotropin family increase the risk of developing ovarian hyperstimulation. This condition is characterized by the overdevelopment of follicles and the formation of large cysts. **Refer to your doctor immediately if:**

- you feel abdominal pain, discomfort or swelling
- you have nausea
- you are vomiting
- you have diarrhea
- you gain weight
- you have breathing difficulties.

Your doctor may instruct you to stop using this medicine (see section 4). This condition may be less likely to develop if the recommended dose and schedule of administration are strictly followed.

**Blood clotting problems** (thromboembolic events; thromboembolism)- Blood clots (in the veins or arteries) are more likely to occur in women who are pregnant. Fertility treatments may increase the risk of developing this condition, especially if you are overweight or if you have a family history of blood clotting disease (thrombophilia). Inform your doctor if this applies to you.

**Twisting of ovaries-** There have been reports of twisting of ovaries (ovarian torsion) following fertilization treatments. Twisting of the ovary can cut off the blood flow to the ovary.

**Multiple pregnancy and birth defects-** When undergoing fertility treatments, the probability of having a multiple pregnancy mainly depends on the number of embryos transferred to the womb, the quality of the embryos and your age. Multiple pregnancy may lead to medical complications for you and your babies. Furthermore, the risk of birth defects may be higher following fertility treatments. The increased risk is attributed to characteristics of the parents (such as age and your partner's sperm characteristics) and to multiple pregnancy.

**Pregnancy loss-** The risk of miscarriage following fertility treatment is higher than in the case of a natural pregnancy.

**Ectopic pregnancy (pregnancy outside the uterus)-** After undergoing fertility treatment, the risk of an ectopic pregnancy is higher than if you conceive naturally. If you have a history of tubal disease, you have an increased risk of ectopic pregnancy.

**Ovarian and other reproductive system tumors-** There have been reports of ovarian and other reproductive system tumors in women who underwent fertility treatments. It is not known if treatment with fertility medicines increases the risk of these tumors in infertile women.

### **Other medical conditions**

**Before treatment with this medicine, tell your doctor if:**

- you have been told by another doctor that pregnancy would endanger your health
- you have kidney or liver disease

**Children and adolescents (up to 18 years of age):** This medicine is not intended for children and adolescents.

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell your doctor.**

**Pregnancy and Breastfeeding:** Do not use this medicine if you are pregnant or breastfeeding.

**Driving and use of machinery:** This medicine does not affect your ability to drive and use machines.

**Important information about some of the ingredients of this medicine:** The medicine contains less than 23 mg sodium per dose, i.e. essentially "sodium-free".

### **3. How to Use This Medicine**

Always use according to the doctor's instructions.

Check with your doctor or pharmacist if you are not sure.

The dosage and manner of treatment will be determined only by your doctor.

#### **Do not exceed the recommended dose.**

The dosage of Rekovele for your first treatment cycle will be calculated by your doctor using your AMH levels and your weight. AMH (anti-Mullerian hormone) is a marker of how your ovaries will respond to treatment. Therefore, the AMH results taken within the last 12 months need to be available before you start treatment. Your body weight will also be measured before you start treatment. The Rekovele dose is stated in micrograms.

The Rekovele dose is fixed for the whole treatment period, with no daily dose adjustments. Your doctor will monitor the results of the treatment with Rekovele and will stop the treatment once you reach the required number of follicles. Usually, you will be given a single injection of a medicine called hCG at a dose of 250 micrograms or 5,000 IU to complete the maturation process of the follicles.

If your body's response to treatment is too weak or too strong, your doctor may stop treatment with Rekovele and change your daily dose of Rekovele for the next treatment cycle.

### **How to inject**

The injection instructions must be followed strictly. Do not use the pen if the solution contains particles or is not clear.

The first injection of this medicine is to be given under the supervision of a doctor or a nurse. Your doctor will decide whether you can inject yourself at home, but only after receiving adequate training.

The injection is given subcutaneously, usually in the abdominal area. The pen can be used for multiple injections.

**If you have accidentally injected an overdose or if a child has accidentally swallowed the medicine,** proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. The effects of an overdose with this medicine are unknown. Ovarian hyperstimulation syndrome may occur (see section 4).

**If you forgot to receive this injection** at the intended time, do not take a double dose. Contact your doctor as soon as you notice that you forgot to take the medicine. Persist with the treatment as recommended by your doctor. Do not stop treatment with the medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose **each time** you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine, ask your doctor or pharmacist.

### **4. Side Effects**

As with any medicine, the use of Rekovele may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

#### **Serious side effects:**

Hormones used for the treatment of fertility problems such as this medicine may cause hyperstimulation of the ovaries (ovarian hyperstimulation syndrome). Symptoms can include pain, abdominal discomfort or swelling, nausea, vomiting, diarrhea, weight gain or breathing difficulties. If you have any of these symptoms- **refer to your doctor immediately.**

#### **Other side effects:**

**Common side effects** (side effects that appear in 1-10 users out of 100)

- Headache
- Nausea
- Ovarian hyperstimulation syndrome (see above)
- Pelvic pain and discomfort, including in the area of the ovaries
- Tiredness (fatigue)

**Uncommon side effects** (side effects that appear in 1-10 users out of 1000)

- Mood swings
- Sleepiness
- Dizziness
- Diarrhea
- Vomiting
- Constipation
- Discomfort of the abdomen
- Vaginal bleeding
- Breast pain and tenderness

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

#### **Reporting of side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website ([www.health.gov.il](http://www.health.gov.il)), which directs to the online form for reporting side effects, or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### **5. How to Store the Medicine**

**Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package and the pen label. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C), do not freeze.

Before first use, store in the original package in order to protect from light. The medicine may be removed from the refrigerator and stored at a temperature of up to 25°C for up to 3 months but must not be refrigerated again.

If you have not used the package within 3 months, it must be discarded.

After first use, the pen may be stored for up to 28 days at a temperature of up to 25°C.

At the end of the treatment discard any unused solution. Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

### **6. Additional Information**

**In addition to the active ingredient, the medicine also contains:**

Phenol, polysorbate 20, L-methionine, sodium sulphate decahydrate, disodium hydrogen phosphate dodecahydrate, concentrated phosphoric acid, sodium hydroxide and water for injections

**What the medicine looks like and contents of the package:**

The preparation is a clear and colorless solution for injection in a multi-dose pen.

The **Rekovele 36** package contains one multi-dose pen and 6 needles for injection.

The **Rekovele 72** package contains one multi-dose pen and 9 needles for injection.

#### **Registration holder and address:**

Ferring Pharmaceuticals Ltd., 8 Hashita St., Industrial Park Caesarea 3088900

#### **Manufacturer and address:**

Ferring GmbH, Germany

This leaflet was checked and approved by the Ministry of Health in 11/2017.

**Drug registration number at the national medicines registry of the Ministry of Health:**

**Rekovele 36** registration number 159-61-35097

**Rekovele 72** registration number 159-62-35098

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