Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Rekovelle 12/36/72

Solution for injection under the skin

Composition: Each Rekovelle 12 multi-dose pen contains 12 mcg follitropin delta
Each Rekovelle 36 multi-dose pen contains 36 mcg follitropin delta
Each Rekovelle 72 multi-dose pen contains 72 mcg follitropin delta

Inactive ingredients - See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.
If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.
This medicine is intended for adult women over 18 years old.

1. What is this medicine intended for?

Rekovelle is a medicine that contains follitropin delta. This is a follicle stimulating hormone which belongs to the family of hormones called gonadotropins. Gonadotropins are involved in reproduction and fertility.
Rekovelle is used in the treatment of women undergoing assisted reproduction programmes such as *in vitro* fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) micromanipulation.
Rekovelle stimulates the ovaries to produce several follicles from which eggs are collected and fertilised in the laboratory.

Therapeutic group: gonadotropins

2. Before using this medicine

Before starting treatment, you and your partner in the fertility treatment process must be checked by a fertility specialist.

Do not use this medicine if:

- you are sensitive (allergic) to follitropin delta or any of the inactive ingredients in this medicine (see section 6)
- you have a tumour of the uterus, ovaries, breasts, pituitary gland or hypothalamus
- you have enlarged ovaries or cysts on your ovaries (unless caused by polycystic ovarian syndrome)
- you have vaginal bleeding for an unknown reason
- you have had an early menopause
- you have malformations of the reproductive organs which make a normal pregnancy impossible
- you have fibroids of the uterus (tumours that are not cancer) which make a normal pregnancy impossible.

Special warnings about using this medicine

Ovarian hyperstimulation syndrome. Gonadotropins medicines increase the risk of developing ovarian hyperstimulation syndrome. This is a condition in which follicles develop too much and large cysts are formed. **Contact your doctor immediately if:**
- you have abdominal pain, discomfort or swelling
- you have nausea
- you are vomiting
- you have diarrhoea
- you gain weight
- you have difficulty in breathing.

Your doctor may tell you to stop using this medicine (see section 4). Being careful to follow the recommended dose and schedule of administration may reduce the chance of developing this reaction.

Blood clotting problems (cases of thromboembolism). Blood clots (in veins or arteries) are more likely in women who are pregnant. Fertility treatment can increase the risk of this happening, especially if you are overweight or you or have a family history of a blood clotting disease (thrombophilia). Tell your doctor if this applies to you.

Twisting of ovaries. There have been reports of twisting of ovaries (ovarian torsion) following fertility treatments. Twisting of the ovary could cut off the blood flow to the ovary.

Multiple pregnancy and birth defects. When undergoing fertility treatment the possibility of having a multiple pregnancy is mainly related to the number of embryos implanted, 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 treatment. This increased risk is thought to be due to characteristics of the parents (such as your age, and your partner's sperm characteristics) and multiple pregnancy.

Pregnancy loss. There is a greater risk of miscarriage following fertility treatment than if you conceive naturally.

Pregnancy outside the uterus. There is a greater risk of pregnancy outside the uterus following fertility treatment than if you conceive naturally. If you have a history of tubal disease, you have an increased risk of pregnancy outside the uterus.

Ovarian and other reproductive organ tumours. There have been reports of ovarian and other reproductive organ tumours in women who had undergone fertility treatment. It is not known if treatment with fertility medicines increases the risk of these tumours in infertile women.

Other medical conditions
Before starting treatment with this medicine, tell your doctor if:
- you have been told by another doctor that pregnancy would be dangerous to your health
- you have kidney or liver disease

Children and adolescents (under 18 years of age): This medicine is not indicated in children and adolescents.

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breast-feeding: Do not use this medicine if you are pregnant or breast-feeding.
Driving and using machines: This medicine does not affect your ability to drive and use machines.
Important information about some of this medicine's ingredients: This medicine contains less than 23 mg sodium per dose, it is therefore considered "sodium-free".

3. How to use this medicine?

Always use according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
Do not exceed the recommended dose.
The Rekovelle dose for your first treatment cycle will be calculated by your doctor using your levels of AMH hormone and your weight. AMH is a marker of how your ovaries respond to treatment so AMH results taken within the last 12 months should be available before you start treatment. Your body weight will also be measured before you start treatment. The Rekovelle dose is stated in micrograms.

The Rekovelle dose is fixed for the whole treatment cycle with no adjustments to your daily dose. Your doctor will monitor the effect of Rekovelle treatment, and will stop the treatment when you achieve the required number of follicles. Usually, you will be given a single injection of a medicine called hCG at a dose of 250 mcg or 5,000 IU to complete the follicles' maturation process.
If your body´s response to treatment is too weak or too strong, your doctor may stop treatment with Rekovelle, and change the daily dose of Rekovelle in your next treatment cycle.

How are injections given.
Carefully follow the instructions for injection. Do not use the pen if the solution contains particles or is not clear.
The first injection of this medicine should be given under the supervision of a doctor or a nurse. Your doctor will decide if you can give yourself the injections at home, but only after receiving adequate training.
The injection is given under the skin usually in the abdomen area. The pen can be used for several injections.
If you accidentally inject an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room, and bring the medicine package with you. The effects of an overdose of this medicine are unknown. Ovarian hyperstimulation syndrome may possibly occur (see section 4).
If you forget to get an injection at the scheduled time, do not take a double dose. Contact your doctor as soon as you notice that you forgot to take your medicine. Adhere to the treatment as recommended by your doctor. Do not stop taking this medicine without consulting a doctor first.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Rekovelle may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects
Hormones used in the treatment of infertility such as this medicine may cause a high level of activity in the ovaries (ovarian hyperstimulation syndrome). Symptoms may include pain, discomfort or swelling of the abdomen, nausea, vomiting, diarrhoea, weight gain or difficulty breathing. If you experience any of these symptoms, **contact a doctor immediately.**

Other side effects:

Common side effects (affect 1-10 in 100 users)
- headache
- nausea
- ovarian hyperstimulation syndrome (see above)
- pelvic pain and discomfort, including of ovarian origin
- tiredness (fatigue)

Uncommon side effects (affect 1-10 in 1000 users)
- mood swings
- sleepiness
- dizziness
- diarrhoea
- vomiting
- constipation
- discomfort of the abdomen
- vaginal bleeding
- breast pain and tenderness

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
Do not induce vomiting unless explicitly instructed to do so by a doctor.

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

Storage conditions: Keep refrigerated (2ºC-8ºC). Do not freeze.
Store in the original package in order to protect from light. This medicine may be taken out of the refrigerator and stored at or below 25ºC for up to 3 months, but do not put it back in the refrigerator. Discard the pack if you have not used it within 3 months.
After first use, you can store the pen for up to 28 days at or below 25ºC.

At the end of treatment any unused solution must be discarded. Do not throw away any medicine down the drain or in the bin. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this 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 pack:
This medicine is a clear and colourless solution in a pre-filled multi-dose pen.
Rekovelle 12 packs contain 1 multi-dose pre-filled pen and 3 injection needles.
Rekovelle 36 packs contain 1 multi-dose pre-filled pen and 6 or 9 injection needles.
Rekovelle 72 packs contain 1 multi-dose pre-filled pen and 9 or 15 injection needles.

Registration holder's name and address:
Ferring Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park, Caesarea 3088900

Manufacturer's name and address: Ferring GmbH Germany

This leaflet was revised in September 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Rekovelle 12 registration number 159-60-35096
Rekovelle 36 registration number 159-61-35097
Rekovelle 72 registration number 159-62-35098

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