Package leaflet: Information for the user

REKOVELLE 36 micrograms/1.08 mL solution for injection in a pre-filled pen
follitropin delta

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What REKOVELLE is and what it is used for
2. What you need to know before you use REKOVELLE
3. How to use REKOVELLE
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1. What REKOVELLE is and what it is used for

REKOVELLE contains follitropin delta, 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 female infertility and in women undergoing assisted reproduction programmes such as *in vitro* fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). REKOVELLE stimulates the ovaries to grow and develop many egg sacs (‘follicles’), from which eggs are collected and fertilised in the laboratory.

2. What you need to know before you use REKOVELLE

Before starting treatment with this medicine, a doctor should check you and your partner for possible causes of your fertility problems.

Do not use REKOVELLE
- if you are allergic to follicle stimulating hormone or any of the other ingredients of this medicine (listed in section 6)
- if you have a tumour of the uterus, ovaries, breasts, pituitary gland or hypothalamus
- if you have enlarged ovaries or cysts on your ovaries (unless caused by polycystic ovarian disease)
- if you suffer from bleeding from the vagina without any known cause
- if you have had an early menopause
- if you have malformations of the sexual organs which make a normal pregnancy impossible
- if you have fibroids of the uterus which make a normal pregnancy impossible.

Warnings and precautions
Talk to your doctor before using REKOVELLE.

Ovarian hyperstimulation syndrome
Gonadotropins like this medicine may cause ovarian hyperstimulation syndrome. This is when your follicles develop too much and become large cysts.
Talk to your doctor if you:
- have abdominal pain, discomfort or swelling
- have nausea
- are vomiting
- get diarrhoea
- gain weight
- have difficulty in breathing

Your doctor may ask you to stop using this medicine (see section 4).
If the recommended dose and schedule of administration are followed, ovarian hyperstimulation syndrome is less likely.

Blood clotting problems (thromboembolic events)
Clots in the blood vessels (veins or arteries) are more likely in women who are pregnant. Infertility treatment can increase the risk of this happening, especially if you are overweight or you or someone in your family (blood relative) have a known blood clotting disease (thrombophilia). Tell your doctor if you think this applies to you.

Twisting of ovaries
There have been reports of twisting of ovaries (ovarian torsion) following assisted reproductive technology treatment. Twisting of the ovary could cut off the blood flow to the ovary.

Multiple pregnancy and birth defects
When undergoing assisted reproductive technology treatment the possibility of having a multiple pregnancy (such as twins) is mainly related to the number of embryos placed inside your 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 slightly higher following infertility treatment, which 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
When undergoing assisted reproductive technology treatment, you are more likely to have a miscarriage than if you conceive naturally.

Pregnancy outside the uterus (ectopic pregnancy)
When undergoing assisted reproductive technology treatment, you are more likely to have a pregnancy outside the uterus (ectopic pregnancy) 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 tumours
There have been reports of ovarian and other reproductive system tumours in women who had undergone infertility treatment. It is not known if treatment with fertility medicines increase the risk of these tumours in infertile women.

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

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

Other medicines and REKOVELLE
Tell your doctor if you are using, have recently used or might use any other medicines.

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 you're ability to drive and use machines.

REKOVELLE contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to use REKOVELLE

Always use this medicine exactly as your doctor has told you and at the dose your doctor has told you. Check with your doctor if you are not sure.

The REKOVELLE dose for your first treatment cycle will be calculated by your doctor using the level of anti-Müllerian hormone (AMH, a marker of how your ovaries will respond to stimulation with gonadotropins) in your blood and your body weight. Therefore the AMH result from a blood sample (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 period with no adjustments to increase or decrease your daily dose. Your doctor will monitor the effect of REKOVELLE treatment, and treatment is stopped when an appropriate number of egg sacs are present. In general, you will be given a single injection of a medicine called human chorionic gonadotrophin (hCG) at a dose of 250 micrograms or 5,000 IU for final development of the follicles.

If your body´s response to treatment is too weak or too strong, your doctor may decide to stop treatment with REKOVELLE. For the next treatment cycle, your doctor will in this case give you either a higher or a lower daily dose of REKOVELLE than before.

How are injections given
The instructions for using the pre-filled pen must be followed carefully. Do not use the pre-filled pen if the solution contains particles or if the solution does not look 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 further doses of this medicine at home, but only after receiving adequate training.

This medicine is to be given by injection just under the skin (subcutaneously) usually in the abdomen. The pre-filled pen may be used for several injections.

If you use more REKOVELLE than you should
The effects of taking too much of this medicine are unknown. Ovarian hyperstimulation syndrome may possibly occur, which is described in section 4.

If you forget to use REKOVELLE
Do not take a double dose to make up for a forgotten dose. Please contact your doctor as soon as you notice that you forgot a dose.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 have any of these symptoms you should contact a doctor immediately.

The risk of having a side effect is described by the following categories:

Common (may affect up to 1 in 10 people):
- Headache
- Nausea
- Ovarian hyperstimulation syndrome (see above)
- Pelvic pain and discomfort, including of ovarian origin
- Tiredness (fatigue)

Uncommon (may affect up to 1 in 100 people):
- Mood swings
- Sleepiness/drowsiness
- Dizziness
- Diarrhoea
- Vomiting
- Constipation
- Discomfort of the abdomen
- Vaginal bleeding
- Breast complaints (include breast pain, breast tenderness)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store REKOVELLE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pre-filled pen label and carton after EXP. The expiry date refers to the last day of that month.

Store in refrigerator (2 °C - 8 °C). Do not freeze.
Store in the original package in order to protect from light.

REKOVELLE may be stored at or below 25 °C for up to 3 months including the period after first use. It must not be refrigerated again and must be discarded if it has not been used after 3 months.

After first use: 28 days when stored at or below 25 °C.

At the end of the treatment any unused solution must be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What REKOVELLE contains

- The active substance is follitropin delta.
  Each pre-filled pen with multidose cartridge contains 36 micrograms of follitropin delta in 1.08 millilitre of solution. One millilitre of solution contains 33.3 micrograms of follitropin delta in each millilitre of solution.
- The other ingredients are phenol, polysorbate 20, L-methionine, sodium sulphate decahydrate, disodium phosphate dodecahydrate, concentrated phosphoric acid, sodium hydroxide and water for injections.

What REKOVELLE looks like and contents of the pack

REKOVELLE is a clear and colourless solution for injection in a pre-filled pen (injection). It is available in packs of 1 pre-filled pen and 9 pen injection needles.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.