

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrREKOVELLE®
(follitropin delta injection)
Solution for injection in a prefilled pen

Read this carefully before you start taking **REKOVELLE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REKOVELLE**.

What is REKOVELLE used for?

REKOVELLE is used to treat female infertility and is used in women undergoing assisted reproduction programmes such as in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI).

How does REKOVELLE work?

REKOVELLE stimulates the ovaries to grow and develop many egg sacs / follicles, from which eggs are collected and fertilised in the laboratory (in vitro).

What are the ingredients in REKOVELLE?

Medicinal ingredients: follitropin delta

Non-medicinal ingredients: disodium hydrogen phosphate dodecahydrate, L-methionine, sodium sulphate decahydrate, phenol, polysorbate 20, phosphoric acid, sodium hydroxide, water for injection.

REKOVELLE comes in the following dosage forms:

REKOVELLE is a clear colourless solution for injection. It is provided in a multi-dose prefilled pen.

Pre-filled pens are available in the following strengths and packages:

- 12 µg/0.36 mL Pack of 1 pen and 3 needles
- 36 µg/1.08 mL Pack of 1 pen and 6 needles
- 72 µg/2.16 mL Pack of 1 pen and 9 needles

Do not use REKOVELLE if:

- You are allergic to follicle stimulating hormone or any of the other ingredients of this medicine
- 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 disease)
- You suffer from bleeding from the vagina without any known cause
- You are pregnant or breastfeeding
- You have experienced an early menopause
- You have abnormal shape of the sexual organs which make a normal pregnancy impossible
- You have fibroids of the uterus which make a normal pregnancy impossible.

REKOVELLE should not be used in children and adolescents.

No interaction studies have been performed with REKOVELLE.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REKOVELLE. Talk about any health conditions or problems you may have, including:

Ovarian Hyperstimulation Syndrome (OHSS)

Gonadotropins like REKOVELLE may cause ovarian hyperstimulation syndrome (OHSS). This is when your follicles develop too much and become large cysts.

Talk to your doctor if you:

- Experience abdominal pain, discomfort or swelling
- Experience nausea
- Are vomiting
- Experience diarrhoea
- Gain weight
- Have difficulty in breathing

The doctor may ask you to stop using this medicine.

Blood clotting problems (thromboembolic events)

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 an ovary (Ovarian torsion)

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

Multiple pregnancy and birth defects

When undergoing assisted reproductive technology treatment, the risk of having a multiple pregnancy (such as twins) is mainly related to the number 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 if applicable) and multiple pregnancy.

Pregnancy loss

When undergoing assisted reproductive technology treatment, you are more likely to have a miscarriage than if you conceive naturally.

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

In addition, before starting to use this medicine, tell your doctor if you have been told by a doctor that pregnancy would be dangerous for you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take REKOVELLE:

The separate instructions for using the prefilled pen must be followed carefully. Do not use if the solution contains particles or if the solution is not clear.

REKOVELLE is intended to be given by injection just under the skin (subcutaneously) and the normal administration site is the abdominal wall. The prefilled pen can be used for several injections.

The first injection of this medicine should be given under the supervision of a doctor or a nurse. Hereafter your doctor will decide if you can administer REKOVELLE by self-administration at home, but only after receiving adequate training.

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

Usual dose:

The REKOVELLE dose applicable to 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 daily REKOVELLE dose is fixed throughout the treatment period. Treatment is stopped when an appropriate number of egg sacs are present.

Your doctor will monitor the effect of REKOVELLE treatment. Depending on your response to the treatment, your doctor may decide to stop treatment with REKOVELLE and not give you the hCG injection.

If you use more REKOVELLE than you should:

The effects of taking too much REKOVELLE are unknown. Nevertheless one could expect ovarian hyperstimulation syndrome (OHSS) to occur.

Overdose:

The effects of taking too much REKOVELLE are unknown. Nevertheless one could expect ovarian hyperstimulation syndrome (OHSS) to occur.

If you think you have taken too much REKOVELLE, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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.

What are possible side effects from using REKOVELLE?

These are not all the possible side effects you may feel when taking REKOVELLE. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

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

Serious side effects:

Hormones used in treatment of infertility such as REKOVELLE may cause a high level of activity in the ovaries (ovarian hyperstimulation syndrome, OHSS). 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 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 (OHSS)
- Pelvic pain and discomfort
- Ovarian or tubal pain
- 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)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Ovarian hyperstimulation syndrome (OHSS)		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Do not use this medicine after the expiry date which is stated on the prefilled pen label or carton. The expiry date refers to the last day of that month.

Storage:

Store refrigerated (2°C – 8°C). Do not freeze.

Before use, store in the original package in order to protect from light.

Within the shelf life, the REKOVELLE prefilled pen may be removed from the refrigerator, and stored at or below 25°C for up to 3 months including the 28 day in-use period. After this period, do not refrigerate again and discard the product.

After first injection, store the REKOVELLE prefilled pen at or below 25°C for up to 28 days. After this period, discard the pen. Do not throw away any medicines via household waste. Ask your pharmacist how to dispose of medicines you no longer use.

Keep in a safe place and out of reach and sight of children

If you want more information about REKOVELLE:

- Talk to your healthcare professional
- Find the most recent version of the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; (www.canada.ca/en/health-canada), the manufacturer's website (www.ferring.ca/en/products/), or by calling 1-866-384-1314.

This leaflet was prepared by Ferring Inc.

Last Revised: