**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S4**

**REKOVELLE**® 12 micrograms/0,36 mL solution for injection in a pre-filled pen

**REKOVELLE**® 36 micrograms/1,08 mL solution for injection in a pre-filled pen

**REKOVELLE**® 72 micrograms/2,16 mL solution for injection in a pre-filled pen

Follitropin delta.

Sugar free.

**Read all of this leaflet carefully before you start using REKOVELLE®**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- REKOVELLE® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**



**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* fertilization (IVF) and intracytoplasmic sperm injection (ICSI). REKOVELLE® stimulates the ovaries to grow and develop many egg sacs (‘follicles’), from which eggs are collected and fertilized 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)
- 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 have had an early menopause
- you have malformations of the sexual organs which make a normal pregnancy impossible
- you have fibroids of the uterus which make a normal pregnancy impossible.
- if you are pregnant or are breastfeeding
- REKOVELLE® is not for use by men.

**Warnings and precautions**

**Tell your doctor or healthcare provider before being given the injection 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

There is limited experience on the safety and efficacy in women above 40 years of age.

Safety and efficacy in use for more than 3 cycles has not been established.

Ovarian hyperstimulation syndrome

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

If the recommended dose and schedule of administration are followed, ovarian hyperstimulation syndrome is less likely.

If you are at risk of developing OHSS your doctor may instead consider to give you a medicine called gonadotropin-releasing hormone (GnRH) agonist for final development of the follicles, as the use of a GnRH agonist may reduce (but not completely remove) the risk of OHSS.

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 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.

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 medicine and REKOVELLE®**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

**Pregnancy and breastfeeding**

Do not use this medicine if you are pregnant or are breastfeeding your baby.

**Driving and using machinery**

This medicine does not affect your ability to drive and use machines.

**REKOVELLE® contains sodium.**

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium-free”.

## 3. How to use REKOVELLE®

Do not share medicines prescribed for you with any other person.

Always use REKOVELLE® exactly as your doctor has told you and at the dose your doctor has told you. Check with your doctor or pharmacist 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.

If you have an excessive ovarian response, your doctor may choose to instead of hCG give you an injection of a medicine called gonadotropin-releasing hormone (GnRH) agonist for final development of the follicles. This approach may reduce (but not completely remove) the risk of OHSS. In this case, embryos should not be replaced in the fresh cycle but frozen for later use.

**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**

Ovarian hyperstimulation syndrome may occur, which is described in section 2. Warnings and precautions. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**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**

REKOVELLE® can have side effects.

Not all side effects reported for REKOVELLE® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking REKOVELLE®, please consult your doctor, pharmacist or other healthcare provider for advice.

**Serious side effects:**

REKOVELLE® used in the treatment of infertility 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:

**Frequent**

- Headache
- Nausea
- Ovarian hyperstimulation syndrome (see above)
- Pelvic pain and discomfort, including of ovarian origin
- Tiredness (fatigue)

**Less frequent**

- Mood swings
- Sleepiness/drowsiness
- Dizziness
- Diarrhoea
- Vomiting
- Constipation
- Discomfort of the abdomen
- Vaginal bleeding
- Breast complaints (include breast pain, breast tenderness)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of REKOVELLE®.

## 5. How to store REKOVELLE®

Store all medicine out of 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.

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

After first use: 28 days when stored at or below 30 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 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 12 / 36 / 72 micrograms of follitropin delta in 0,36 / 1,08 / 2,16 milliliter of solution. One milliliter of solution contains 33,3 micrograms of follitropin delta in each milliliter 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).

3 mL multidose cartridge with a plunger and a crimp cap with an inlay (rubber).

The cartridges contain 0,36 ml/ 1,08 ml/ 2,16 ml of solution.

It is available in packs of 1 pre-filled pen and 3 / 9 / 15 pen injection needles.

**Holder of the Certificate of Registration**

Ferring (Pty) Ltd

Route 21 Corporate Park

6 Regency Drive

Irene Ext 30

Pretoria

+27 12 345 6358

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