REKOVELLE®

Solution for injection in pre-filled pen
12 micrograms/0.36 mL
36 micrograms/1.08 mL
72 micrograms/2.16 mL

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What REKOVELLE is used for

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.

How REKOVELLE works

REKOVELLE contains follitropin delta, a follicle stimulating hormone which belongs to the family of hormones called gonadotropins. Gonadotropins are involved in reproduction and fertility.

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.

-when you must not use it

DO NOT take REKOVELLE if:

- you are allergic to follicle stimulating hormone or any of the other ingredients of this medicine (listed in product description section)
- 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.

-Before you start to use it

Check with your doctor before taking REKOVELLE.

REKOVELLE should be used with caution in situation:

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 Side Effects section).
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. 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

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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.

Pregnancy and lactation
Do not use this medicine if you are pregnant or breastfeeding.

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

-Taking other medicines
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
No interaction studies have been performed.

How to use REKOVELLE
-How much to use
Always use REKOVELLE exactly as 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 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.

Instruction for use:
An instruction for use booklet is packed together with REKOVELLE. Read this booklet completely before using your REKOVELLE pre-filled pen and each time you get a new pen. There may be new information. Follow the instructions carefully even if you have used a similar injection pen before. Using the pen incorrectly could result in receiving an incorrect dose of medicine.

The REKOVELLE pre-filled pen is a disposable, dial-a-dose pen that can be used to give more than 1 dose of REKOVELLE.

The instructions for using the REKOVELLE pre-filled pen must be followed carefully. Keep the booklet in case you need to refer to it.

For more information, please refer to Instruction for Use booklet.

-When to use it
Always use REKOVELLE exactly as your doctor has told you. If you are not sure, check with your doctor

-How long to use it
You should continue to use REKOVELLE for as long as your doctor tells you to.

-If you forget to use it
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.

-If you use too much (overdose)
If you use more REKOVELLE than you should seek treatment immediately.

While you are using it
-Things you must do
Use your medicine exactly as your doctor has told you**.**
Tell all the doctors, dentists and pharmacists treating you that you are using REKOVELLE.

-Things you must not do

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- Do not stop using the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give REKOVELLE to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of
This medicine does not affect your ability to drive and use machines. If REKOVELLE make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects
Like all medicines, REKOVELLE 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
- 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

Tell your doctor if you notice any of the side-effects listed or notice any other effects not listed.

You may report any side-effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website: npra.gov.my
[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of REKOVELLE
-Storage
Keep this medicine out of the sight and reach of children.

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. During in use period, keep the pen cap on in order to protect from light.

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

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description
-What it looks like
12mcg/0.36ml:
One prefilled pen contains 12 micrograms of follitropin delta in 0.36 ml of solution. One ml of solution contains 33.3 micrograms of follitropin delta. It is available in packs of 1 pre-filled pen and 3 injection needles.

36mcg/1.08ml:
One prefilled pen contains 36 micrograms of follitropin delta in 1.08 ml of solution. One ml of solution contains 33.3 micrograms of follitropin delta. It is available in packs of 1 pre-filled pen and 6 injection needles.

72mcg/2.16ml:
One prefilled pen contains 72 micrograms of follitropin delta in 2.16 ml of solution. One ml of solution contains 33.3 micrograms of follitropin delta. It is available in packs of 1 pre-filled pen and 9 injection needles.

REKOVELLE is a clear and colourless solution for injection

-Ingredient
-Active Ingredient
Follitropin delta*.
*recombinant human follicle-stimulating hormone (FSH) produced in a human cell line (PER.C6) by recombinant DNA technology.

-Inactive ingredient
Phenol, polysorbate 20, L-methionine, sodium sulphate decahydrate, disodium phosphate dodecahydrate, concentrated

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phosphoric acid, sodium hydroxide
and water for injections.

-MAL number
12mcg: MAL20046095ACZ
36mcg: MAL20046096ACZ
72mcg: MAL20046097ACZ

Manufactured by
Vetter Pharma-Fertigung GmbH &
Co. KG
Schützenstrasse 87, 99-101, 88212
Ravensburg, Germany

Released by
Ferring GmbH,
Wittland 11, 24109 Kiel, Germany

Product Registration Holder
Ferring Sdn Bhd
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Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor

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