

REKOVELLE®

Solution for injection in a pre-filled multidose pen

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using REKOVELLE?

REKOVELLE is used in the treatment of infertility (reproduction related conditions) in women. It contains the active ingredient follitropin delta, which is a recombinant form of human follicle-stimulating hormone (FSH).

For more information, see Section [1. Why am I using REKOVELLE?](#) in the full CMI.

2. What should I know before I use REKOVELLE?

Do not use REKOVELLE if you have ever had an allergic reaction to follitropin delta, or to any of the ingredients listed at the end of the CMI (see Section [7. Product details](#) in the full CMI).

There are several circumstances in which a person should not use this medicine or may need to use it with caution. It is important to understand if any of these apply to you before using REKOVELLE.

Talk to your doctor if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before I use REKOVELLE?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with REKOVELLE and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use REKOVELLE?

- **You should only use REKOVELLE under the supervision of a doctor experienced in the treatment of infertility.**
- Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are unsure. Your doctor will determine your dose of REKOVELLE depending on your condition.

- Before using REKOVELLE, you must be educated on how to use the injection pen and how to perform injections. Your first injection must be supervised by a trained healthcare practitioner.

More instructions can be found in Section [4. How do I use REKOVELLE?](#) in the full CMI and in the ‘Instructions for Use’ booklet inside the carton.

5. What should I know while using REKOVELLE?

<p>Things you should do</p>	<ul style="list-style-type: none"> • Tell any doctor, dentist or pharmacist you visit that you are using REKOVELLE. • Be sure to keep all your doctor’s appointments so your progress can be checked regularly.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop using this medicine or change the dose without talking to your doctor. • Do not give your medicine to anyone else, even if they have the same condition as you.

Looking after your medicine

- Store REKOVELLE in a refrigerator (2°C to 8°C). Do not freeze.
- Always store the REKOVELLE pre-filled pen with the cap on, to protect from light.
- After opening, the REKOVELLE pre-filled pen may be stored at or below 25°C for up to 28 days.

For more information, see Section [5. What should I know while using REKOVELLE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects.

Pain and/or swelling in the abdomen or pelvic region, nausea, vomiting, diarrhoea, weight gain, having difficulty breathing and/or reduced urination may be a sign of too much activity in the ovaries and may require urgent medical attention in hospital. For more information see Section [6. Are there any side effects?](#) in the full CMI.

REKOVELLE®

Solution for injection in a pre-filled multidose pen

Active ingredient: *follitropin delta*

Consumer Medicine Information (CMI)

This leaflet provides important information about using REKOVELLE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using REKOVELLE.**

Where to find information in this leaflet:

- [1. Why am I using REKOVELLE?](#)
- [2. What should I know before I use REKOVELLE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use REKOVELLE?](#)
- [5. What should I know while using REKOVELLE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using REKOVELLE?

REKOVELLE is used in the treatment of infertility (reproduction related conditions) in women. It belongs to a class of medicines called gonadotrophins.

REKOVELLE contains the active ingredient follitropin delta, which is a recombinant form of human follicle-stimulating hormone (FSH).

REKOVELLE is used to stimulate the ovaries to grow and develop egg sacs ('follicles'), from which eggs are collected and fertilised in the laboratory.

REKOVELLE is used to stimulate the follicles in women undergoing Assisted Reproductive Technology (ART) procedures to help them become pregnant. ART procedures include IVF/ET (*in vitro* fertilisation/embryo transfer), and ICSI (intracytoplasmic sperm injection).

2. What should I know before I use REKOVELLE?

Warnings

Do not use REKOVELLE if:

- you are allergic to follitropin delta, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant or breastfeeding
- you have cancer of the uterus (womb), ovaries, or breasts
- you have a tumour of the pituitary gland or hypothalamus
- you have enlarged ovaries or cysts on your ovaries not caused by polycystic ovarian syndrome (PCOS)

- you have had bleeding from the vagina where the cause is not known
- your ovaries have failed
- you have malformations of the sexual organs, which make a normal pregnancy impossible
- you have fibroids, or tumours, of the uterus (womb) which make a normal pregnancy impossible.

Do not use the REKOVELLE pre-filled pen if:

- the expiry date printed on the pack has passed
- the solution contains particles
- the solution does not look clear.

Tell your doctor if you:

- have or have had any other medical conditions, especially the following:
 - thyroid problems
 - high prolactin levels in the blood
 - blood clots, a history of blood clots, or any condition that puts you at risk of blood clots
 - polycystic ovarian syndrome (PCOS)
 - ovarian hyperstimulation syndrome (OHSS)
 - fallopian tube disease.
- take any medicines for any other condition.

Your doctor will assess you and your partner's fertility. This may include tests for other medical conditions, including medical conditions which may interfere with your ability to become pregnant. If necessary, other

medical conditions may be treated before starting infertility treatments including the use of REKOVELLE.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use REKOVELLE if you are pregnant or breastfeeding.

It may affect your developing baby if you use it during pregnancy. Talk to your doctor immediately if you become pregnant while using REKOVELLE.

Pregnancy risks

- The risk of a pregnancy outside of the womb (ectopic pregnancy) may be higher after assisted reproduction than if you conceive naturally. If you have a history of tubal disease, you have an increased risk of ectopic pregnancy.
- Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing fertility treatments.
- Multiple pregnancy, more than one baby at a time, carries greater risks for mothers and babies. In patients undergoing ART procedures, the risk of multiple pregnancy is related to the number of embryos replaced, their quality and your age. Your doctor will monitor your response to treatment to minimise the chance of multiple pregnancies.

- There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures.

Some women who have been given multiple medicines for infertility treatment have developed tumours in the ovaries and other reproductive organs. It is not yet known if treatment with hormones like REKOVELLE causes these problems.

Ovarian hyperstimulation syndrome (OHSS)

Some people have an exaggerated response to hormones used in ART, including REKOVELLE. This may lead to ovarian hyperstimulation syndrome (OHSS). This is when your follicles develop too much, causing your ovaries to swell and become painful.

Talk to your doctor if you have:

- abdominal pain, discomfort or swelling
- nausea
- vomiting
- diarrhoea
- weight gain
- difficulty in breathing
- decreased urination.

Blood clots

Tell your doctor if you or a family member have or have had blood clots or signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg).

Blood clots are more likely to form inside your blood vessels when you are pregnant. This is more likely if you have had treatment to help you become pregnant and:

- you are overweight (BMI > 30 kg/m²)
- you have a condition that increases your risk of having blood clots ('thrombophilia')
- you or someone in your family (blood relative) has had blood clots.

Twisting of ovaries

Tell your doctor immediately if you experience a sudden pain in your lower abdomen, followed by nausea and vomiting during treatment with REKOVELLE.

There have been reports of twisting of ovaries (ovarian torsion) following assisted reproductive technology treatment. If untreated, twisting of the ovary could cut off the blood flow and damage the ovary.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with REKOVELLE and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REKOVELLE.

4. How do I use REKOVELLE?

Treatment with REKOVELLE should be started under the supervision of a specialist doctor experienced in the treatment of infertility.

How much to use

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are unsure.

Your dose of REKOVELLE and length of treatment will be determined by your doctor depending on your condition. Your dose of REKOVELLE for the first cycle will be determined for you depending on your weight and your fertility as measured by a diagnostic test.

Your REKOVELLE dose is intended to be fixed for the treatment cycle with no adjustments to increase or decrease your daily dose. Your doctor may adjust your dose for any subsequent treatment cycle depending on your response to the last treatment cycle with REKOVELLE.

Follow the instructions provided and use REKOVELLE until your doctor tells you to stop.

When to use REKOVELLE

- Your doctor will advise you when to start REKOVELLE.
- You will need to inject REKOVELLE once a day.
- Your doctor will monitor you with ultrasound alone or may also use blood tests to check when enough follicles are present.
- Usually enough follicles have developed, on average, 9 days after starting treatment however this can range from 5 to 20 days.
- If enough follicles have developed, you will be given another medicine to stimulate the final maturation of the eggs in the follicles prior to collection and fertilisation.
- Your doctor will monitor the effect of REKOVELLE treatment. If you have responded too strongly to REKOVELLE, your doctor may advise you to stop treatment with REKOVELLE and not give you the medicine to stimulate the final maturation of the eggs. In this case, you will be instructed to use a barrier

method of contraception (e.g. condom) or not have sexual intercourse until your next period has started.

How to inject REKOVELLE

- REKOVELLE is to be injected under the skin of your abdomen using a new area of the abdomen on each occasion.
- Before using REKOVELLE, you must be educated on how to use the injection pen and how to perform injections.
- Your first injection must be supervised by a trained healthcare practitioner.
- Step-by-step instructions on how to inject REKOVELLE with the injection pen are provided in the 'Instructions for Use' booklet in the carton.

Do not self-inject REKOVELLE until you are sure of how to do it.

If you forget to use REKOVELLE

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose to make up for the dose you missed.

If you use too much REKOVELLE

REKOVELLE may cause hyperstimulation of the ovaries known as ovarian hyperstimulation syndrome (OHSS). OHSS is a potentially serious complication of infertility treatment and could be fatal without proper

management in hospital. The initial symptoms may consist of abdominal pain, abdominal swelling and/or nausea and vomiting.

If you think that you have used too much REKOVELLE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REKOVELLE?

Things you should do

Call your doctor straight away if you:

- feel pain in the abdomen or pelvic region
- notice swelling in the abdomen
- experience nausea (feeling sick) or vomiting
- develop diarrhoea
- gain weight
- have trouble breathing
- notice you are urinating less.

Tell your doctor straight away if you notice any of the above symptoms, even if the symptoms develop some days after the last injection has been given.

This can be a sign of high levels of activity in the ovaries known as OHSS and the symptoms could become severe.

If these symptoms become severe, treatment with REKOVELLE should be stopped and you should receive urgent medical attention in hospital.

Keeping to your recommended dose and careful monitoring of your treatment will reduce your chances of getting these symptoms.

You should also contact your doctor right away if you:

- become pregnant
- have unusual vaginal bleeding.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will normally arrange for you to have ultrasound scans and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell any doctor, dentist or pharmacist you visit that you are using REKOVELLE. If you are going to have surgery, tell the surgeon or anaesthetist that you are using REKOVELLE.

Things you should not do

- Do not stop using this medicine or change your dose without talking to your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

REKOVELLE should not normally interfere with your ability to drive a car or operate machinery.

Be careful before you drive or use any machines or tools until you know how REKOVELLE affects you.

Looking after your medicine

- Keep REKOVELLE in a refrigerator at a temperature of 2°C to 8°C. Do not freeze.
- Always store the REKOVELLE pre-filled pen in the original package with the cap on to protect from light.
- REKOVELLE may be removed from the refrigerator and stored at or below 25°C for up to 3 months as long as the expiry date has not passed. It must be discarded afterwards.
- After opening, the pre-filled pen can be stored at or below 25°C for up to 28 days. After 28 days, the pre-filled pen containing any unused medicine should be discarded.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Discard REKOVELLE pre-filled pen if it has been opened for more than 28 days.

Do not use this medicine after the expiry date.

Once you have injected REKOVELLE, do not re-use the needle. Discard the used needle into an approved, puncture-resistant sharps container and keep it out of the reach of children. Never put a used needle into your normal household rubbish bin.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it has expired, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Common side effects (affect more than 1 in 100 users):</p> <ul style="list-style-type: none">• headache• nausea• pelvic discomfort or pain• fatigue <p>Uncommon side effects (affect less than 1 in 100 users):</p> <ul style="list-style-type: none">• mood swings• sleepiness• dizziness• diarrhoea• vomiting• constipation• abdominal discomfort• bleeding from the vagina• breast complaints	<p>These side effects are not usually serious but can become serious.</p> <p>Seek immediate medical care if you have any concerns.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction (unknown frequency):</p> <ul style="list-style-type: none"> ● rash, itching or hives on the skin ● swelling of the face, lips, tongue or other parts of the body ● shortness of breath, wheezing or difficulty breathing <p>Ovarian hyperstimulation syndrome (OHSS) (common):</p> <ul style="list-style-type: none"> ● stomach pain and/or swelling ● pelvic pain ● nausea or vomiting ● diarrhoea ● rapid weight gain (due to fluid accumulation) ● shortness of breath ● passing less urine 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects, even if a few days have passed since your last injection, or you have stopped using REKOVELLE.</p>

Serious side effects	What to do
<p><i>Rare complications of OHSS:</i></p> <ul style="list-style-type: none"> • blood clots (thromboembolism) • twisting of the ovaries (ovarian torsion) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What REKOVELLE contains

Active ingredient (main ingredient)	follitropin delta
Other ingredients (inactive ingredients)	phenol polysorbate 20 methionine sodium sulfate decahydrate dibasic sodium phosphate dodecahydrate phosphoric acid sodium hydroxide water for injections.

Do not use this medicine if you are allergic to any of these ingredients.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What REKOVELLE looks like

REKOVELLE is a clear and colourless solution for injection in a pre-filled pen and comes in three presentations, 12 micrograms, 36 micrograms and 72 micrograms:

REKOVELLE 12 micrograms pack contains:

1 x pre-filled multidose pen containing 12 micrograms of follitropin delta (rhu) in 0.36 mL of solution for injection and 3 x injection needles (AUST R 289310)

REKOVELLE 36 micrograms pack contains:

1 x pre-filled multidose pen containing 36 micrograms of follitropin delta (rhu) in 1.08 mL of solution for injection and 9 x injection needles (AUST R 289311)

REKOVELLE 72 micrograms pack contains:

1 x pre-filled multidose pen containing 72 micrograms of follitropin delta (rhu) in 2.16 mL of solution for injection and 15 x injection needles (AUST R 289312)

Who distributes REKOVELLE

REKOVELLE is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street, Pymble NSW 2073

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