

For patients who have been prescribed Rekovelle® by a doctor

This patient guide contains information about the Rekovelle pre-filled pen. Step-by-step instructions will guide you through the preparation and proper handling of the pen.

If you have any questions about using Rekovelle, ask your doctor or nurse.

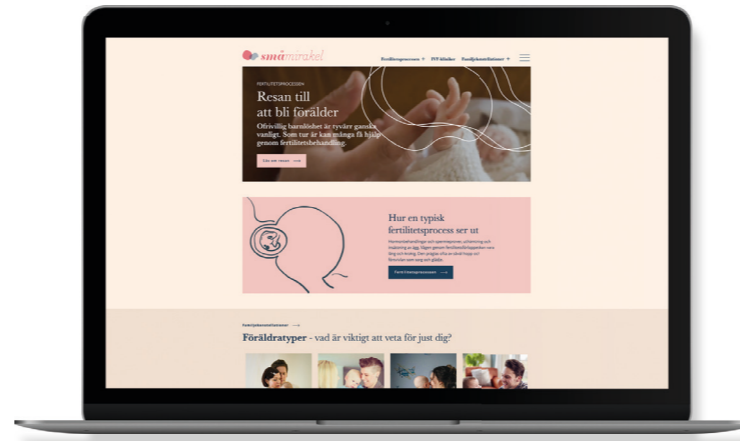
Before the first injection your healthcare provider will instruct you on how to prepare and administer injections with the Rekovelle pre-filled pen.

Read the package leaflet and instructions for use included in the package before you use the Rekovelle pre-filled pen.

Important about storage

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date 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 to 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: Use within 28 days. Store 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.

småmirakel.se



A site about the journey to becoming a parent

The wait for a small miracle can be long and emotional. During fertility treatment, you may also need to learn a lot of new things. At småmirakel.se, we guide you through the fertility process with facts, articles and information.

REKOVELLE® 12 microg/0.36 ml, 36 microg/1.08 ml, 72 microg/2.16 ml (follitropin delta), solution for injection in pre-filled pen. Rekovelle is used in treatment of female infertility and in women undergoing assisted reproduction programmes. Rekovelle stimulates the ovaries to grow and develop more follicles. Before starting treatment, a fertility assessment should be done and possible contraindications to pregnancy investigated. Rekovelle should not be used by women with tumors in the uterus, ovaries, breasts, pituitary gland or hypothalamus, gynecological bleeding without a known cause, enlarged ovaries or cysts on the ovaries or during pregnancy and breastfeeding. The treatment may cause overstimulation of the ovaries (ovarian hyperstimulation syndrome (OHSS)). Consult a doctor if you experience pain, discomfort or swelling in the abdomen, nausea, vomiting, diarrhea or weight gain, or breathing problems. Treatment with Rekovelle may lead to an increased risk of blood clots, especially if you are overweight or if someone in the family has a blood clotting disorder. Read the package leaflet carefully before use, this is also available at www.fass.se. The medicine is a prescription medicine. Always consult a doctor before using the medicine. ATC code: G03GA10. Rx, (F) Rekovelle is not subsidized for social reasons. Ferring Läkemedel AB, 203 11 MALMÖ. Phone: 040-6916900, www.ferring.se



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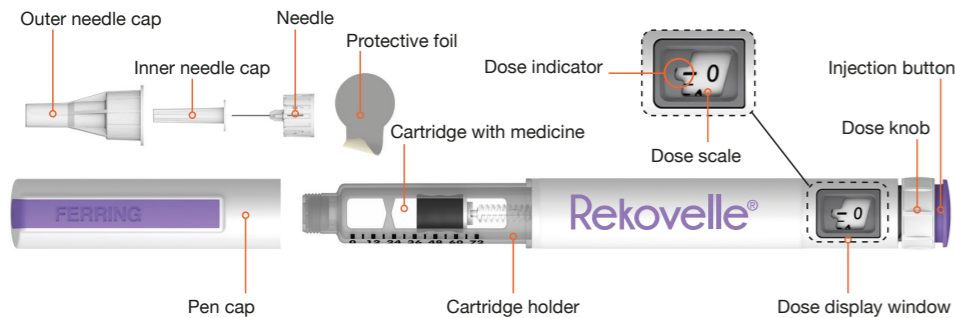
Rekovelle®
follitropin delta



PATIENT GUIDE

Rekovelle® solution for injection in a pre-filled pen

Rekovellev[®] pre-filled pen – the different parts



Rekovellev pre-filled injection pen is a pen with a dose scale, which can be used to give more than 1 dose of Rekovellev.

The injection pen is available in three different amounts of micrograms

- 12 microgram/0,36 ml
- 36 microgram/1,08 ml
- 72 microgram/2,16 ml

The injection pen can be set to deliver doses from 0,33 micrograms to 20 micrograms of Rekovellev in marked increments of 0,33 micrograms.

The Rekovellev injection pen should only be used after you have been instructed by your healthcare professional.



You can watch the Rekovellev instruction video on this website (or by scanning the QR code).

www.medicininstruktioner.se/ferring/rekovellev



Step-by-step instructions for using the Rekovellev[®] pre-filled pen

Wash your hands with soap and water before using the Rekovellev injection pen.

1) Insert the needle



Pull off the pen cap and remove the protective foil from the needle. Click the needle so that it is securely attached. Always use a new needle for each injection.

3) Preparation



Turn the dose knob clockwise until the droplet symbol lines up with the dose indicator. Hold the pen with the needle pointing upwards. Lightly tap the cartridge holder with your finger so that any air bubbles in the cartridge rise to the top. **Only prime your pen the first time you use it.** If the pen has already been used – proceed directly to “Set the dose” on the next page.

2)



Pull off the outer needle cap. Do not throw it away, as it will be used again. Pull off the inner needle cap and throw it away.

4)



When the needle is pointing upwards, press the injection button as far as it will go until you see the number “0” lined up with the dose indicator. Check that a small drop forms at the tip of the needle. If a drop does not appear, repeat steps 3 and 4.

The Rekovellev[®] pre-filled injection pen is now ready to use.

5) Set the dose



Turn the dose knob clockwise until the prescribed dose appears next to the dose indicator in the dose display window. The dose can be increased or decreased without loss of drug.

7) Dose injection



Rekovellev should be given by injection under the skin in the stomach region. Use a new injection site for each injection to reduce the risk of skin reactions. Clean the injection site with an alcohol swab. Pinch the skin firmly and insert the needle into the skin. Once the needle is inserted, place your thumb on the injection button. **Push the injection button all the way in. Wait for 5 seconds after the number “0” appears lined up with the dose indicator. This ensures you get the full dose.** Release the injection button, then slowly remove the needle from the injection site by pulling it straight out of the skin.

6) Split dose

You may need more than one injection pen to get the prescribed dose. If you cannot select the full dose, it means that there is not enough medicine left in the pen. If necessary, you can give a split-dose injection or discard the current pen and use a new pen for the injection.

See the package insert for more detailed information on calculating the split dose.

8) Removing the needle



Carefully place the outer needle cap over the needle with firm pressure. Unscrew the needle counterclockwise to remove the needle from the injection pen. Carefully discard the used needle.

Always remove the needle after each use.

Insert the pen cap

Press the pen cap onto the injection pen for protection between injections.

Dispose of used needles in a sharps container immediately after use. Do not dispose of the container with household waste.