

Please hand this leaflet to patients receiving this medicine.

For users of Rekovellev[®] Pen for Subcutaneous Injection

Your doctor should explain how to use and handle this injection pen.

Be sure to read this leaflet completely before use.

If you have any concerns, stop using the Rekovellev[®] pre-filled pen and call your doctor or pharmacist immediately.



Your dose is _____ μg , once daily.

The dose indicator should line up with:

- exactly
- the first thin line after (1 tick turned)
- the second thin line after (2 ticks turned)

_____ in the display window.

You can watch a video of how to inject on our website.



https://www.ferring.co.jp/rekovellev-movie/pen_easy_en/
Associated communication fee is borne by the viewer.

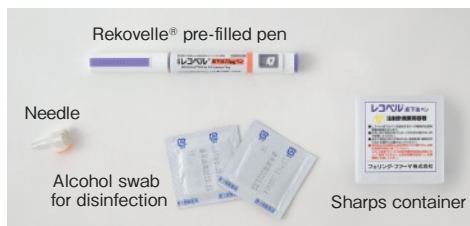
FERRING

PHARMACEUTICALS

Items necessary for injection

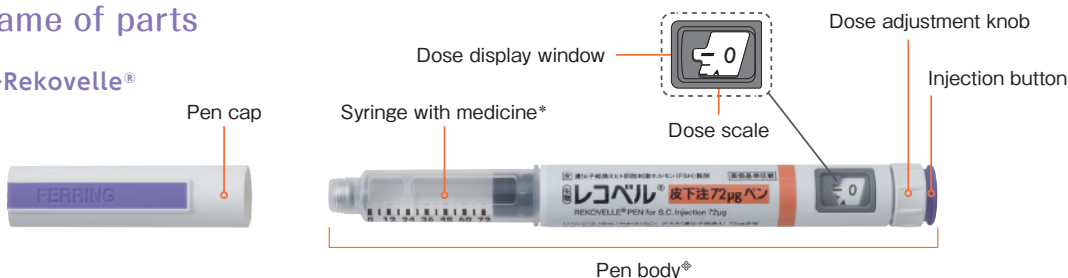
Set up on a clean surface to prepare.

Rekovellev[®] pre-filled pen and needles are only for you and should not be shared with others. Use needles prescribed by your doctor.

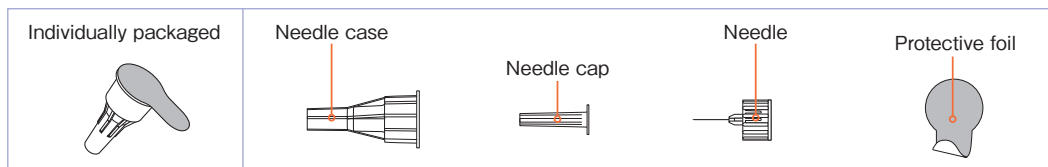


Name of parts

◆Rekovellev[®]



◆Needle Use with Rekovellev[®] pre-filled pen.



*Medicine: liquid containing the active ingredient, follitropin delta
 ◆The color of label indicates different amount of medicine.

Self-injection procedures

STEP 1 Wash your hands

Wash your hands with **soap** before preparing for injection.

STEP 2 Attach the needle



1 Pull off the **pen cap**.



2 Wipe the rubber stopper at the tip of the pen with the alcohol swab to disinfect.

*Do not wrap the whole tip with the swab. If disinfectant remains on the tip as the needle is attached, the needle may not detach after use.



3 Pull off the protective foil from the needle cap.
 *Use a fresh needle for each injection.



4 Hold the needle case with one hand and the pre-filled pen with the other, **place the needle on straight** and insert it **lightly while turning clockwise**.

*If it is properly attached, you will feel a click. If inserted too deeply, the needle may not be removed.

STEP 3 Priming

Before using a new pen (for the first time), You need to **remove air bubbles in the cartridge (priming)**. If the pen has been primed (second time on), go to **STEP 4**.



1 Pull off the **needle case**.

*Do not discard the **needle case**, as you will use it to remove the needle.



2 Pull off the **needle cap**.

*Immediately discard the **needle cap**.

! After removing the cap, be careful not to touch the **needle** with your fingers or objects.



3 Turn the dose knob until the **droplet icon** lines up with the dose indicator.

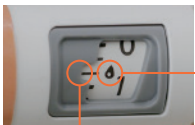
* If "0" does not appear with a new pen, it is not a problem. Line up the dose indicator with the droplet icon.



4 With the needle pointing upwards, tap the cartridge holder with your finger to make air bubbles in the cartridge gather at its tip.

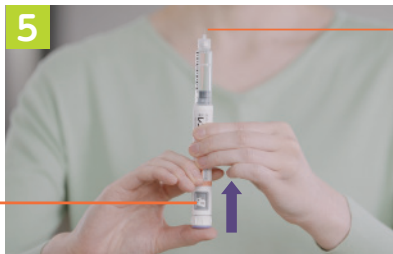
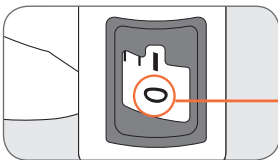


If even small bubbles do not rise to the tip, proceed to **5** below. Also, even if you see no bubbles, follow the same procedure.



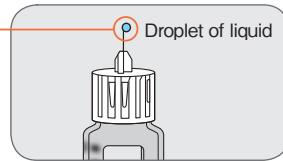
Droplet icon

Dose indicator



5

Droplet of liquid

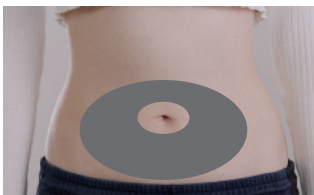


With the needle still pointing upward (away from your face), press the injection button until the number "0" lines up with the dose indicator and check that **a droplet of liquid** comes out of the needle tip.

If no droplet comes out, repeat priming (**3** to **5** of **STEP 3**) until it comes out.

*If no droplet comes out even after repeating 5 times, remove the needle (see **STEP 7**), attach a new one (see **STEP 2**) and repeat priming again.

STEP 4 Select an injection site and wipe with an alcohol swab



Select an injection site and wipe **about 5 cm around** the site with an alcohol swab.

* Avoid injecting where you feel any tenderness, pain, or redness.

You will be injecting in the **abdomen** (gray area). Use a **new injection site each time**.

Example 1: Inject in the right abdomen one day and the left abdomen on the next day.

Example 2: A site should be away at least 3 cm from the injection site of last time.

STEP 5 Dial in the dose



Turn the dose knob until the prescribed dose lines up in the dose indicator.

*You can turn the knob either clockwise or counterclockwise.

The dose can be set in increments of $0.33 \mu\text{g}$. One tick between the numbers corresponds to $0.33 \mu\text{g}$.

Please be careful not to press the injection button while dialing the dose.



If you turn the knob too much, turn in the opposite direction to line up the indicator with correct dose.

! If you cannot turn the knob to the prescribed dose, that means there is not enough remaining medicine. In this case, use another pen for injection. For injection with insufficient medicine, refer to “[Instruction for self-injection at home](#)”.

STEP 6 Inject the dose



Pull off the needle case and needle cap.

*After priming, they have been removed; go to **2**.

You will need the **needle case** to remove the needle; **do not discard**. You may **discard** the removed **needle cap**.



Pinch the skin of disinfected area with two fingers. Hold the pen with the other hand **so you can see the dose display window**. Insert the needle **straight and completely**.

After the needle is inserted completely, press the injection button with your thumb. After the **number “0”** lines up with the dose indicator, **hold the button down for 5 seconds**.



Wait for 5 seconds with “0” lined up



Remove your thumb from the injection button and pull out the needle slowly and straight. Place an **alcohol swab** on the injection site and press firmly. In case of bleeding, keep pressing with an alcohol swab.

*If blood is visible in the cartridge, use a new pen for the next injection.

STEP 7 Discard the needle



Place the needle case over the needle and remove the needle from the pen by turning the cap counterclockwise.

*Needle should be removed after every injection.



Discard the needle in the sharps container.

STEP 8 Attach the pen cap



Attach the pen cap firmly for protection. You cannot attach the cap with the needle on the pen.

Rekovellev[®] is “follicle stimulating hormone (FSH) medicine” to promote growth of eggs in the ovaries.*1

- The active ingredient of Rekovellev[®] is **FSH**, a hormone produced from human cells that promotes the growth of eggs in the ovaries.
- **Your Rekovellev[®] dose will be prescribed** based on your **AMH*2** value and body weight.
- You inject it **by yourself** subcutaneously **once a day, starting several days after your period starts.**

*1: Electronic package insert for Rekovellev[®] Pen for Subcutaneous Injection

*2: AMH: anti-Mullerian hormone, secreted from small growing follicles (bag-like tissue wrapping eggs).

Rekovellev[®]'s adverse reaction: Ovary hyperstimulation syndrome (OHSS)*3

If eggs (follicles) grow more than expected and the ovaries are overstimulated by Rekovellev[®]'s effects, symptoms such as swelling of the ovaries to retain fluid in the abdomen or chest may occur. It is called **ovary hyperstimulation syndrome (OHSS)**, the side effect to pay the most attention with Rekovellev[®].

*3: Drug information sheet for Rekovellev[®] Pen for Subcutaneous Injection

Main initial symptoms of OHSS (pay special attention from first injection to 2 weeks after finishing injection of Rekovellev[®])



Severe pain on lower abdomen (pelvic pain)



nausea, vomiting



steep weight gain



tightening or discomfort of lower abdomen, growing waist size



reduced urine volume



Diarrhea

If you have any of the symptoms above, stop using Rekovellev[®] and contact your doctor or pharmacist immediately.

Other side effects:

- Swollen ovaries (ovarian enlargement)

You may have symptoms such as tightening or discomfort in the abdomen, lower back pain, lower abdominal pain, or constipation.

- Fluid retention in pelvis (pelvic fluid collection)

You may have symptoms such as tightening in the abdomen, or abdominal pain.

Even with symptoms other than above, if you have worrying symptoms or have any concerns, please consult your doctor or pharmacist.

Your medical facility

Ferring Pharmaceuticals medicine support office

If you have questions on Rekovelle®, Please call:



0120-093-168 * Office hours: 9:00 – 17:30
(except for Saturdays, Sundays, Holidays, Company holidays)

*Toll-free number, available from cell phones and PHS. With an IP phone, toll-free may not be available. (JAPANESE ONLY)

Ferring Pharmaceuticals Co., Ltd.