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Size	
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Changes	4th def: requested by NPRA to remove Ferring Denmark address as manufacturer not related to MY
	☐ CCDS version: ☐ SPC country/version/date: ☐ Core PIL version: ☐ LAC no.:
Name & Date	JIWO, 12-Mar-2020

FERRING
PHARMACEUTICALS

Instructions for Use REKOVELLE® (follitropin delta) Pre-filled pen



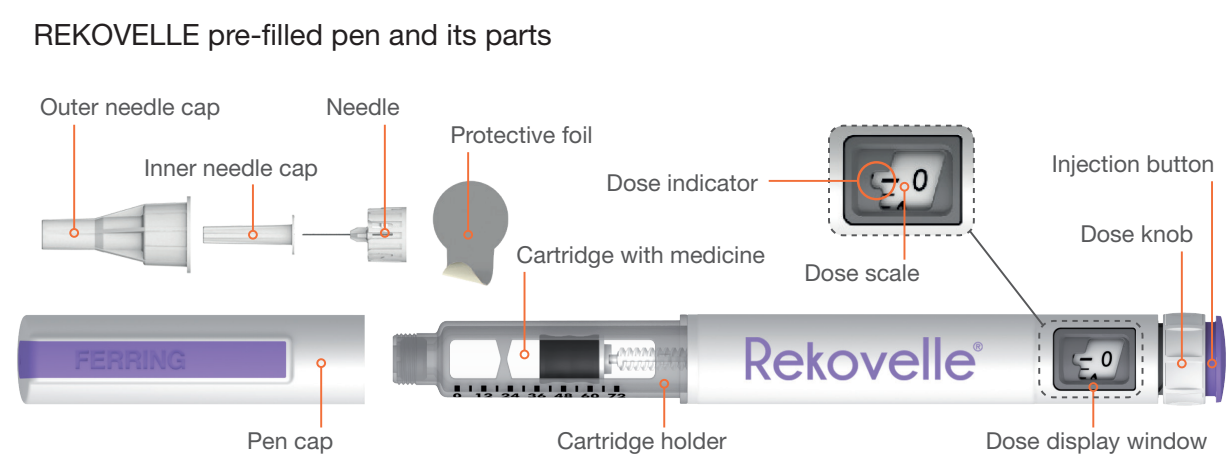
Your healthcare provider should show you how to prepare and inject REKOVELLE the right way before you inject it for the first time.

Do not try to inject yourself until you have been shown the right way to give your injections by your healthcare provider. 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.

Call your healthcare provider (doctor, nurse or pharmacist) if you have any questions about how to give your REKOVELLE injection.

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 pen is available in 3 different strengths:

- **12 micrograms/0.36 mL**
- **36 micrograms/1.08 mL**
- **72 micrograms/2.16 mL**



Instructions for Use

REKOVELLE® (follitropin delta) Pre-filled pen

Warnings

- **Do not** use a pen if it has been dropped or hit against hard surfaces.
- If the injection button is not easy to push in, do not use force. Change the needle. If the injection button still is not easy to push in after changing the needle, use a new pen.
- **Do not** try to repair a damaged pen. If a pen is damaged, contact your healthcare provider or local representative of the marketing authorisation holder (please refer to patient information leaflet for contact details).

Additional information

Needles

Needles are supplied with your pen. If you need additional needles contact your healthcare provider. Use only needles that come with your REKOVELLE pre-filled pen or that your healthcare provider prescribes.

Contact

If you have any questions or problems related to the pen, contact your healthcare provider or local representative of the marketing authorisation holder (please refer to patient information leaflet for contact details).



Instructions for use - REKOVELLE (follitropin delta) pre-filled pen

Important

- The REKOVELLE pre-filled pen and the needles are for use by only one person and should not be shared with others.
- Use the pen only for the medical condition it is prescribed for and as directed by your healthcare provider.
- If you are blind or have poor eyesight and cannot read the dose scale on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the pen.
- Call your healthcare provider or local representative of the marketing authorisation holder (please refer to patient information leaflet for contact details) before giving your REKOVELLE injection if you have questions.

Information about your REKOVELLE pre-filled pen

The pen can be dialed to give doses from 0.33 micrograms to 20 micrograms of REKOVELLE in marked increments of 0.33 micrograms. See “Examples of how to dial a dose” at Page 20 to 21.

- The dose scale of the pen is numbered from 0 to 20 micrograms.
- Each number is separated by two lines, each line is equal to one increment of 0.33 micrograms.

- When turning the dial to your dose, you will hear a click sound and feel resistance on the dial for each increment to help you dial the correct dose.

Cleaning

- If needed, the outside of your pen may be cleaned with a cloth moistened with water.
- **Do not** put the pen in water or any other liquid.

Storage

- Always store the pen with the pen cap on and without a needle attached.
- **Do not** use the pen after the month of expiration (EXP) printed on the pen label.
- **Do not** store the pen in extreme temperatures, direct sunlight or very cold conditions, such as in a car or freezer.
- Store the pen out of the reach of children and anyone who has not been trained to use the pen.

Before use:

- Store the pen in a refrigerator at 2 °C to 8 °C. Do not freeze.

After first use (in-use period):

- The pen may be stored for up to 28 days at or below 30 °C.

Supplies you will need to give your REKOVELLE injection



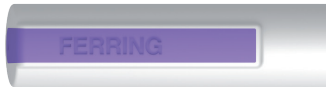
1 x alcohol swab

1 x sterile gauze or
cotton ball



1 x needle
(Supplied with the pen)

1 x puncture-resistant
container

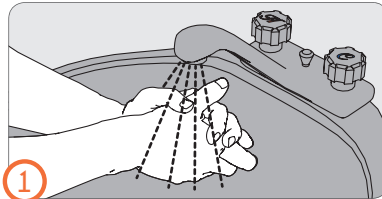


REKOVELLE pre-filled pen

Before use - (Step 1)

①

- Wash your hands.
- Check the pen to see that it is not damaged. Do not use the pen if it is damaged.
- Check the pen (cartridge) to see that the medicine is clear and does not contain particles.
Do not use a pen with particles or unclear medicine in the cartridge.
- Make sure you have the correct pen with correct strength.
- Check the expiration on the pen label.



Rekovele® XX mcg/X.XX mL

Injection

follitropin delta

Subcutaneous use

After first use: Use within 28 days.
Store at or below 30°C.

FERRING Batch: SHF2017
EXP: (MM.YYYY)

Strength
Month of expiration

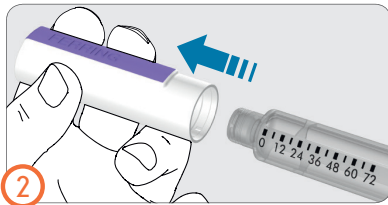
Attaching needle - (Step 2 to 6)

Important:

- **Always** use a new needle for each injection.
- **Only** use the single-use click-on needles supplied with the pen.

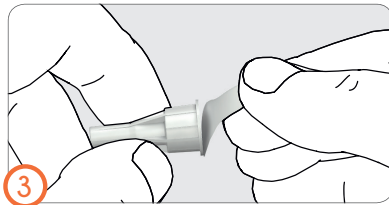
2

- Pull off the pen cap.



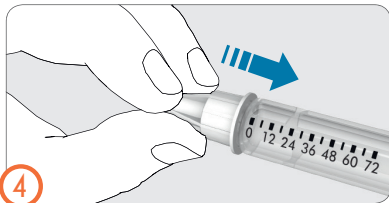
3

- Pull off the protective foil from the needle.



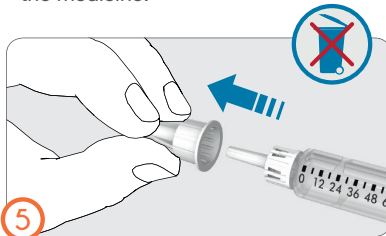
4

- Click on the needle.
- You will hear or feel a click when the needle is safely on.
- You may also screw on the needle. When you feel a light resistance it is safely on.



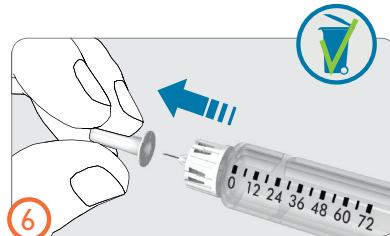
5

- Pull off the outer needle cap.
- **Do not throw the outer needle cap away.** You will need it to throw away (dispose of) the needle after injecting the medicine.



6

- Pull off the inner needle cap and throw it away.

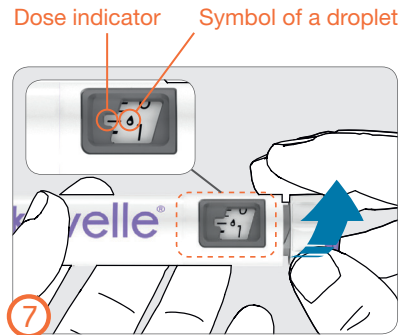


Priming - (Step 7 to 9)

- Before using the pen for the first time, you need to remove air bubbles from the cartridge (**Priming**) to receive the correct dose of medicine.
- **Only prime** your pen the **first time you use it**.
- Perform Step 7 to 9 even if you do not see air bubbles.
- If the pen has **already been used** proceed directly to **Step 10**.

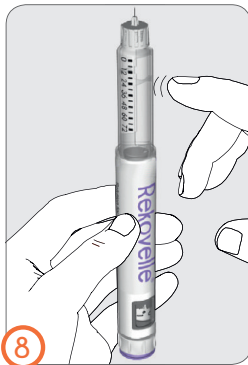
7

- Turn the dose knob clockwise until a **symbol of a droplet** lines up with the dose indicator.
- If you dial the incorrect priming dose, the priming dose can be corrected either up or down without loss of medicine by turning the dose knob in either direction until the symbol of a droplet lines up with the dose indicator.



8

- Hold the pen with the needle pointing upwards.
- Tap with your finger on the cartridge holder to make any air bubbles in the cartridge rise to the top of the cartridge.



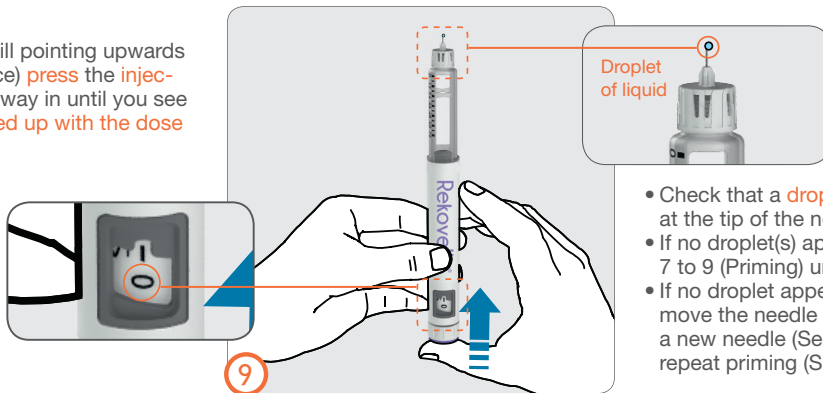
Step 9
on next page



Priming - (Step 7 to 9)

9

- With the needle still pointing upwards (away from the face) **press the injection button** all the way in until you see the number '0' lined up with the dose indicator.



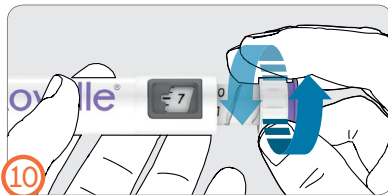
- Check that a **droplet of liquid** appears at the tip of the needle.
- If no droplet(s) appear repeat Steps 7 to 9 (Priming) until a droplet appears.
- If no droplet appears after 5 tries, remove the needle (See Step 13), attach a new needle (See Steps 3 to 6), and repeat priming (See Steps 7 to 9).

Dialing the dose - (Step 10)

10

- Turn the dose knob clockwise until the prescribed dose **lines up with the dose indicator** in the dose display window.
- The dose can be corrected either up or down without loss of medicine by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
- **Do not** press the injection button when dialing the dose to avoid loss of medicine.

- See “Examples of how to dial a dose” at Page 20 to 21.



Split-dosing

- You may need more than one pen to complete your prescribed dose.
- If you are not able to dial your complete dose, this means there is not enough medicine left in the pen. You will need to give a split-dose injection or throw away (dispose of) your current pen and use a new pen for your injection.

See “Giving a split-dose of REKOVELLE” at Page 22 to 23 for examples of how to calculate and record your split dose.

Injecting the dose - (Step 11 to 12)

Important:

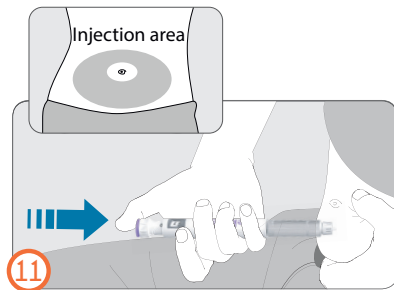
- **Do not** use the pen if the medicine contains particles or if the medicine is not clear.
- **Read Step 11** and **12** at Page 14 to 15 before giving your injection.
- This medicine should be given by injection just under the skin (subcutaneously) in the **stomach-area** (abdomen).
- Use a new injection site for each injection to lower the risk of skin reactions as redness and irritation.
- **Do not** inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.

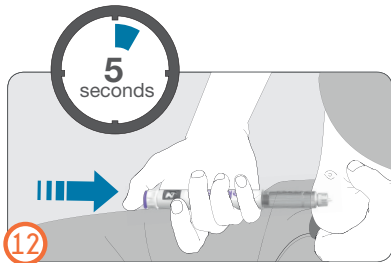
Step **11** & **12** 
on next pages

Injecting the dose - (Step 11 to 12)

11

- Wipe the skin of your injection site with an alcohol swab to clean it. Do not touch this area again before you give your injection.
- Hold the pen so the dose display window is visible during injection.
- Pinch your skin and **insert the needle straight into your skin** as shown by your healthcare provider. Do not touch the injection button yet.
- After the needle is inserted, place your thumb on the injection button.
- **Press the injection button all the way in and hold.**
- **Keep pressing** the injection button in and when you see the **number '0' lined up with the dose indicator**, wait for **5 seconds** (slowly count to 5). This will make sure you get your full dose.





12

- After pressing in the injection button for 5 seconds, release the injection button. Then slowly remove the needle from the injection site by pulling it straight out of the skin.
- If blood appears at the injection site, press a gauze pad or cotton ball lightly to the injection site.

Note:

- Do not tilt the pen during injection and removal from skin.
- Tilting the pen can cause the needle to bend or break off.
- If a broken needle remains stuck in the body or remains under the skin, get medical help right away.

Disposal of needle - (Step 13)

13

- Carefully replace the outer needle cap over the needle with a firm push (A).
- **Unscrew** the needle in counter-clock-wise direction to remove the needle from the pen (B+C).
- **Throw away** (dispose of) the used needle carefully (D).
- See “Disposal” at Page 18.



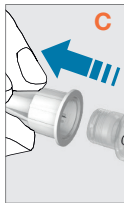
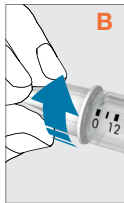
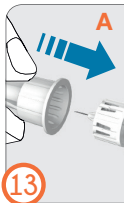
Outer needle cap



Inner needle cap

Note:

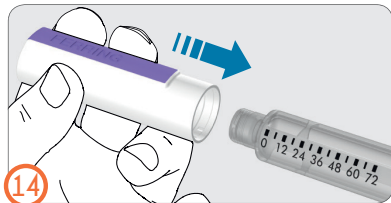
- **Always** remove the needle after every use. The needles are for single-use only.
- **Do not** store the pen with the needle attached.



Replace pen cap - (Step 14)

14

- Firmly replace the pen cap on the pen for protection between injections



Note:

- The pen cap will not fit over a needle.
- If you will give a split-dose injection, only throw away (dispose of) the pen when it is empty.
- If you will use a new pen to give your full prescribed dose instead of giving a split-dose injection, throw away (dispose of) your pen when there is not enough medicine in the pen for a full dose.
- Keep the pen cap on the pen when it is not in use.

Disposal

Needles:

Put your used needles in a puncture-resistant container, such as a sharps disposal container right away after use.

Do not throw away (dispose of) your used sharps disposal container in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,

- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles.

REKOVELLE pre-filled pens:

- Throw away (dispose of) your used pens in accordance with local waste regulations.

On the following pages, you will find more information on the subjects below:

- Examples of how to dial a dose page 20 to 21
- Giving a split-dose of REKOVELLE page 22
- Split-dose diary page 23

As well as:

- Frequently Asked Questions (FAQ)..... page 24
- Warnings..... page 25
- Additional information page 25



Examples of how to dial a dose

Examples of how to dial a dose using your **REKOVELLE** pre-filled pen.



The chart to the right shows examples of prescribed doses, how to dial the examples of prescribed doses, and what the dose display window looks like for the prescribed doses.

Examples of prescribed dose (in micrograms)	0.33	0.66 (priming dose)
Dose to dial on pen	0 and 1 line (Dial to 0 plus 1 click)	0 and 2 lines (Dial to 0 plus 2 clicks)
Dose display window for example of prescribed dose		

2.33	11.00	12.33	18.66	20.00
2 and 1 line (Dial to 2 plus 1 click)	11 (Dial to 11)	12 and 1 line (Dial to 12 plus 1 click)	18 and 2 lines (Dial to 18 plus 2 clicks)	20 (Dial to 20)
				

Giving a split-dose of REKOVELLE

If you are not able to dial the full prescribed dose in your pen, this means that there is not enough medicine left in the pen to give the full dose. You will need to give part of your prescribed dose using your current pen and the remainder of the dose using a new pen (split-dose injection) or you may throw away (dispose of) the pen you are using and use a new pen to give your full prescribed dose in 1 injection. If you decide to give a split-dose injection, follow these instructions and write down how much medicine to give using the [split-dose diary](#) on [Page 23](#).



- Column **A** shows an example of a prescribed dose. Write down your prescribed dose in column **A**.
- Column **B** shows an example of the dose that is left in the pen (this is equal to what you are able to dial).
- Write down the dose that is left in your pen in column **B**. Give the injection using the rest of the medicine that is left in your pen.
- Prepare and prime a new pen (Step 1 to 9).
- Calculate and write down the remaining dose to inject in column **C** by subtracting the number in column **B** from the number in column **A**. Use a calculator to check your math if needed.
- See “Examples of how to dial a dose” at Page 20 to 21 if needed.
- Doses should be rounded off to nearest increment, X.00, X.33 or X.66 micrograms. For example, if the number in column **C** is 5.34, round your remaining dose to 5.33. If the number in column **C** is 9.67, round your remaining dose to 9.66.
- Call your healthcare provider if you have questions about how to calculate your split-dose.
- Inject the remaining dose of medicine (the number in column **C**) using your new pen to complete your prescribed dose.

Split-dose diary

A Prescribed Dose	B Dose left in pen (Dose shown at dose indicator in dose display window)	C = A minus B Dose to inject on new pen (Dose shown at dose indicator in dose display window)
11.33	4.00 (4)	7.33 (7 and 1 line (Dial to 7 plus 1 click))
12.66	12.33 (12 and 1 line (12 plus 1 click))	0.33 (0 and 1 line (Dial to 0 plus 1 click))
11.00	3.00 (3)	8.00 (8 (Dial to 8))
12.00	6.66 (6 and 2 lines (6 plus 2 clicks))	Round 5.34 to 5.33 (5 and 1 line (Dial to 5 and 1 click))
18.33	8.66 (8 and 2 lines (8 plus 2 clicks))	Round 9.67 to 9.66 (9 and 2 lines (Dial to 9 plus 2 clicks))

Frequently Asked Questions (FAQ)

1. Is the priming step necessary before each injection?

- No. Priming must be performed only before giving the first injection with a new pen.

2. How do I know that the injection is complete?

- The injection button is firmly pushed in all the way until it stops.
- The number '0' is lined up with the dose indicator.
- You have slowly counted to 5 while you are still holding the injection button in and the needle is still in your skin.

3. Why do I have to count to 5 while holding the injection button?

- Holding the injection button for 5 seconds allows for the full dose to be injected and absorbed under your skin.

4. What if the dose knob cannot be turned to the required dose?

- The cartridge in the pen may not have enough medicine left to deliver the prescribed dose.
- The pen does not allow you to dial a larger dose than the dose that is left in the cartridge.

- You can inject the medicine left in the pen and complete the prescribed dose with a new pen (**split-dose**) or use a new pen to give the full prescribed dose.

Date: 12 Mar 2020

Title	Booklet REKOVELLE 12,36,72mcg Pre-filled Pen - IFU mock up - MY 10-Oct-2018		
Item N°	N/A	Perigord N°	360819
Proof N°	03	Barcode N°	N/A
Approving Country	MY	Dimensions	175 X 70 mm
Colours	P. Black; P Pro Blue; P Cyan; P Magenta; P Yellow		