INSTRUCTIONS FOR USE

Ovitrelle 250 micrograms
Solution for injection in pre-filled pen
Choriogonadotropin alfa

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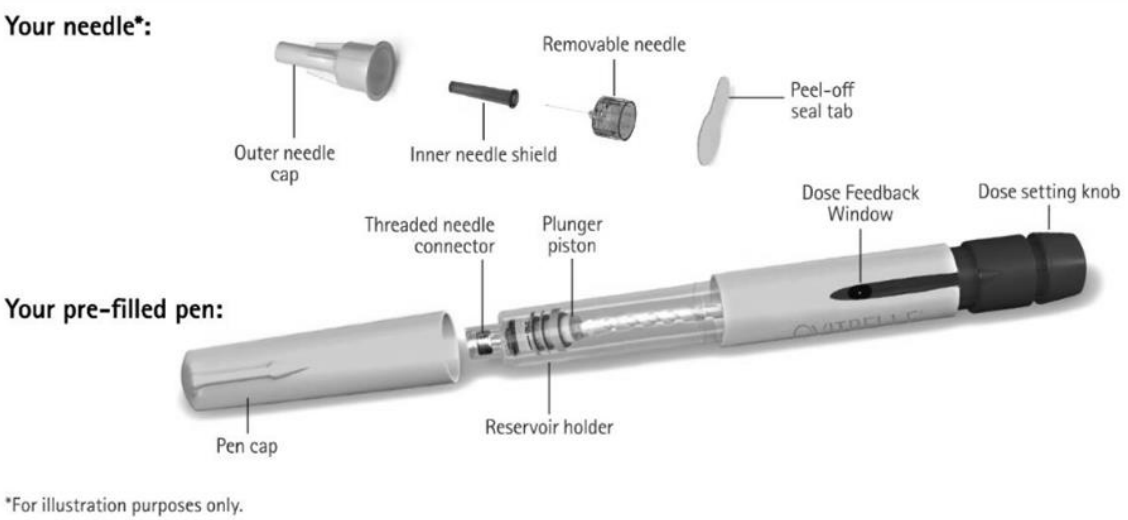
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Important information about the Ovitrelle pre-filled pen

- Read the Instructions for Use and the Package Leaflet before using your Ovitrelle pre-filled pen.
- Always follow all directions in this Instructions for Use and training provided by your healthcare provider as they may differ from your past experience. This information will allow to prevent incorrect treatment or infection by needle stick or broken glass injury.
- The Ovitrelle pre-filled pen is for subcutaneous injection only.
- The Ovitrelle pre-filled pen is for single use only.
- Each Ovitrelle pre-filled pen pack contains one needle for your injection and one spare needle.
- Only use the Ovitrelle pre-filled pen if your healthcare provider trains you on how to use it correctly.
- Store in a refrigerator.

Do not freeze
Do not share the pen and/or needles with another person
Do not use the Ovitrelle pre-filled pen if it has been dropped, or the pen is cracked or damaged as this can cause injury.

Get familiar with your Ovitrelle pre-filled pen



*For illustration purposes only.

Step 1 Gather your supplies

1.1 Prepare a clean area and a flat surface, such as a table or countertop, in a well-lit area.

1.2 You will also need (not included in the pack):
- Alcohol swabs and a sharps container (Figure 1)

1.3 Wash your hands with soap and water and dry them well (Figure 2).

1.4 Use your hand to remove the Ovitrelle pre-filled pen from the pack.


Fig. 1


Fig. 2

Do not use any tools, using tools might damage the pen.

1.5 Check the name on the pre-filled pen says Ovitrelle.
1.6 Check the expiration date on the pen label (Figure 3).



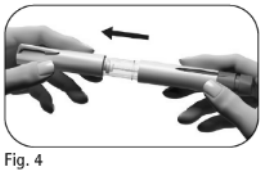
Fig. 3

Do not use the Ovitrelle pre-filled pen if the expiration date has passed or if your pre-filled pen does not say Ovitrelle.

Step 2 Get ready for injection

2.1 Pull-off the pen cap (Figure 4).
2.2 Check that medicine is clear, colourless to slightly yellow and does not contain particles.

Do not use the pre-filled pen if the medicine is discolored or cloudy, as this can cause an infection.


Fig. 4

Choose your injection site:
2.3 Your healthcare provider should show you the injection sites to use around your stomach area (Figure 5).
2.4 Clean the skin at the injection site by wiping with an alcohol swab.

Do not touch or cover the cleaned skin.


Fig. 5

Step 3 Attach your needle

3.1 Get a new needle. Only use one of the single-use needles supplied.
3.2 Check that the outer needle cap is not damaged.
3.3 Hold the outer needle cap firmly.


Fig. 6

3.4 Check that the peel-off seal on the outer needle cap is not damaged or loose, and that the expiration date has not passed. (Figure 6).


Fig. 7

3.5 Remove the peel-off seal (Figure 7).

Do not use the needle if it is damaged, expired or if the outer needle cap or the peel-off seal is damaged or loose. Using expired needles or needles with damaged peel-off seal or outer needle cap can lead to infection. Throw it away in a sharps container, and use the other needle provided in the pack.

Ask your healthcare provider if you have questions.

3.6 Screw the outer needle cap onto the threaded needle connector of the Ovitrelle pre-filled pen until you feel a light resistance (Figure 8).


Fig. 8

Do not attach the needle too tightly; the needle could be difficult to remove after the injection.

3.7 Remove the outer needle cap by pulling it gently (Figure 9).


Fig. 9

3.8 Put it aside for later use (Figure 10).


Fig. 10

Do not discard the outer needle cap, as it will prevent needle stick injury and infection when detaching the needle from the pre-filled pen.

3.9 Hold the Ovitrelle pre-filled pen with the needle pointing upward (Figure 11).
3.10 Carefully remove and discard the green inner shield (Figure 12).


Fig. 11


Fig. 12

Do not recap the needle with the green inner shield, as it can lead to needle stick injury and infection.

3.11 Look closely at the tip of the needle for tiny droplet(s) of liquid.

If	Then
You see a tiny droplet of liquid	Proceed directly to **Step 4: Dial the dose to 250.**
You do not see a tiny droplet at or near the needle tip	You must perform the steps **on the next page** to remove air in the system.

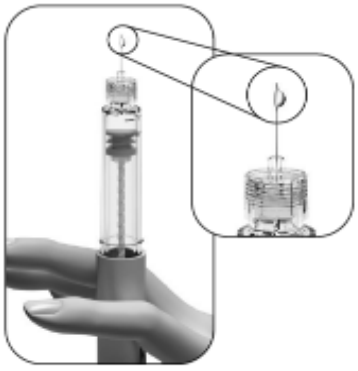


Fig. 13

<u>If you do not see a tiny droplet(s) of liquid at or near the tip when you use a new pen:</u>

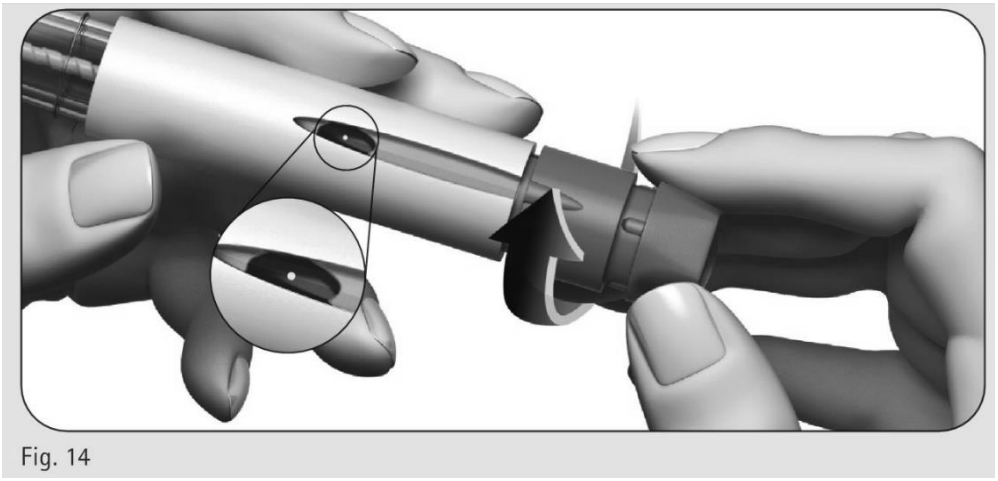


Fig. 14

1. Gently turn the dose setting knob forward until you see a dot (●) in the **Dose Feedback Window** (Figure 14).
- You can turn the dose setting knob backward if you turn it past the dot (●).



Fig. 15

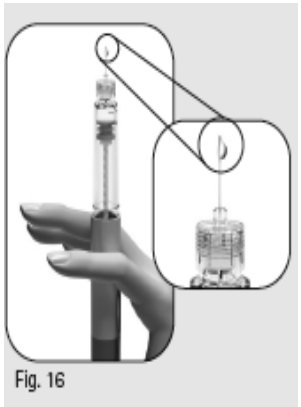


Fig. 16

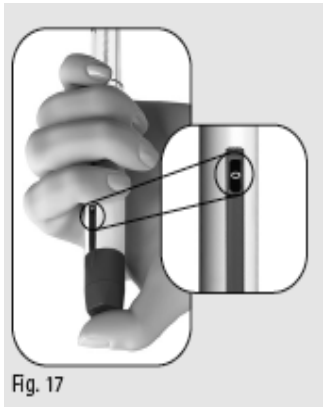


Fig. 17

2. Hold the pen with the needle pointing upward.
3. Tap the reservoir holder gently (Figure 15).
4. Press the dose setting knob **as far as it will go.** A tiny droplet of liquid will appear at the top of the needle (Figure 16)*.
5. Check that the **Dose Feedback Window** reads "0" (Figure 17).

***Note**: If you do not see any liquid, you may restart at step 1(in this section) one more time only. If a tiny droplet of liquid does not appear the second time either, contact your healthcare provider.

Step 4 Dial the dose to 250

4.1 Gently turn the dose setting knob **forward** until **"250"** shows in the Dose Feedback Window.

- The Dose Feedback Window will show a straight line while turning until you can read the number '**250**' (Figure 18).


Fig. 18

Do not push or pull the dose setting button while you turn it.

4.2 Check that the **Dose Feedback Window** displays **"250"** (Figure 19) before you move on to Step 5 below.

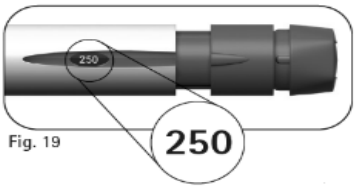


Fig. 19

Contact your healthcare provider if you need help.

Step 5 Inject your dose

Important: Inject the dose as you were trained to do by your healthcare provider.

5.1 Slowly push the needle into the skin entirely (Figure 20).


Fig. 20

5.2 Place your thumb in the middle of the dose setting knob. **Slowly press the dose knob down as far as it will go** and hold it to complete the full injection (Figure 21).

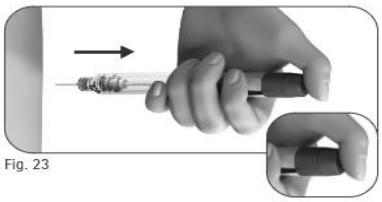

Fig. 21

5.3 Hold the dose knob down for a minimum of 5 seconds before you remove the needle from your skin (Figure 22).

- The dose number shown in the **Dose Feedback Window** will turn back to "0".
- After a minimum of 5 seconds, pull the needle out of the skin **while keeping the dose setting knob pressed down** (Figure 23).
- When the needle is out of the skin, release the dose setting knob.



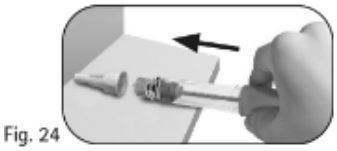
Fig. 22


Fig. 23

Do not release the dose knob until you remove the needle from the skin.

Step 6 Remove the needle after your injection

6.1 Place the outer needle cap on a flat surface.

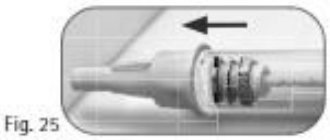

Fig. 24

6.2 Hold the Ovitrelle pre-filled pen firmly with one hand and slip the needle into the outer needle cap (Figure 24).

6.3 Continue by pushing the capped needle against a firm surface until you hear a "click" (Figure 25).

6.4 Grip the outer needle cap and unscrew the needle by turning it in the opposite direction (Figure 26).

6.5 Dispose of the used needle safely in a sharps container (Figure 27). Handle the need with care to avoid getting injured by the needle.


Fig. 25

Do not reuse or share any needle with another person.


Fig. 26


Fig. 27

Step 7 After the injection

7.1 Check you have given a complete injection:

- Check that the **Dose Feedback Window** shows "0" (Figure 28)

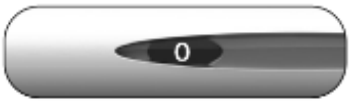


Fig. 28

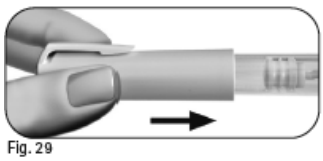
If the Dose Feedback Window shows **"0"**, you have completed your dose.
If the Dose Feedback Window does **not** show **"0"**, please contact your healthcare provider.

Do not attempt to inject a second time.

Step 8 Dispose of the Ovitrelle pre-filled pen

Important: The Ovitrelle pre-filled pen and needles supplied are single-use only.

8.1 Put the pen cap back onto the pen (Figure 29).


Fig. 29

8.2 Ask your healthcare provider how to dispose of the empty Ovitrelle pre-filled pen.

Contact your healthcare provider if you have questions.

This Instructions for Use was last revised in: 11/2022