

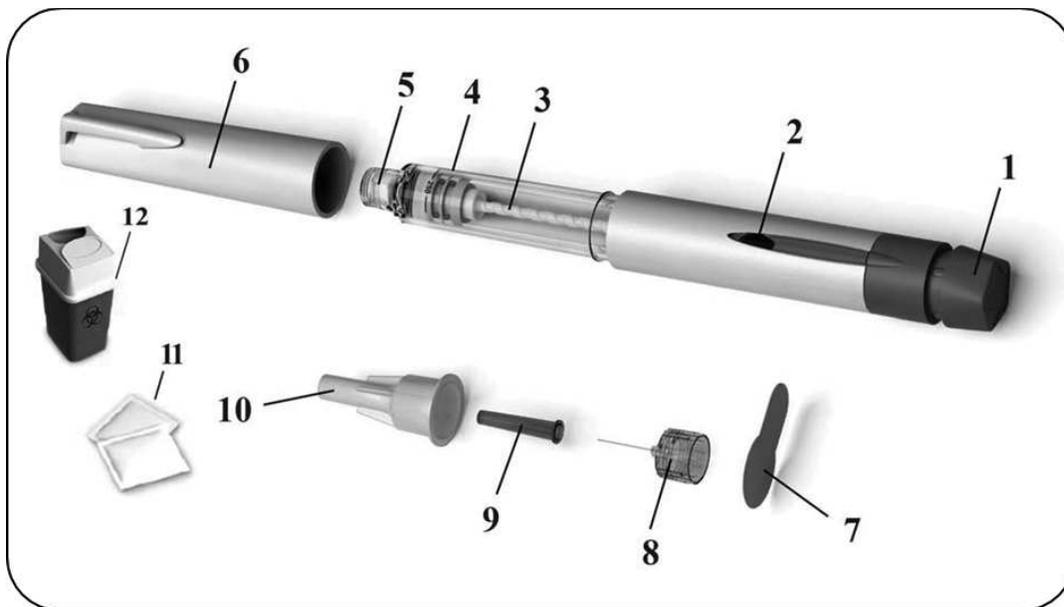
Step 4: Disposal of used Items

Once you have finished your injection, immediately discard the needles and syringe (without recapping the needle) into the disposal container. Take the container to a clinic or pharmacy for proper disposal.

Directions for Administration of OVIDREL in Pre-filled Pen

- This section tells you how to use your pen.
- Do not share the pen. The pen is for subcutaneous injection only.
- Inject OVIDREL as your doctor has taught you.
- **This pen is for single use only.**
- **Please read these directions for use before using your OVIDREL Pen. Follow the procedure exactly, as it may differ from your past experience.**

OVIDREL Pen, and other materials you may need for injection:



- | | | | |
|----|---------------------------|-----|---|
| 1. | Dose Setting Knob | 7. | Peel off seal tab |
| 2. | Dose Display | 8. | Removable needle |
| 3. | Plunger piston | 9. | Inner needle shield |
| 4. | Reservoir holder | 10. | Outer needle cap |
| 5. | Threaded needle connector | 11. | Alcohol wipes (not supplied with the product) |
| 6. | Pen cap | 12. | Sharps disposal container (not supplied with the product) |

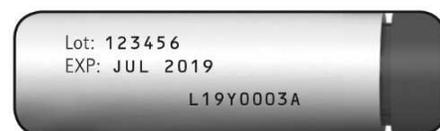
Follow the directions below for injecting OVIDREL

1. Before you start using your OVIDREL Pen

- Wash your hands with soap and water. It is important that your hands and the items you use be as clean as possible.

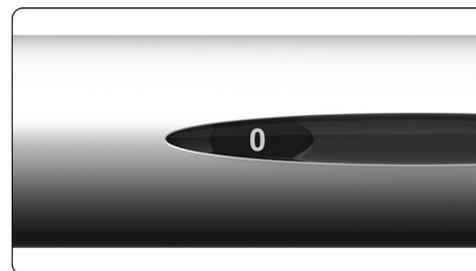
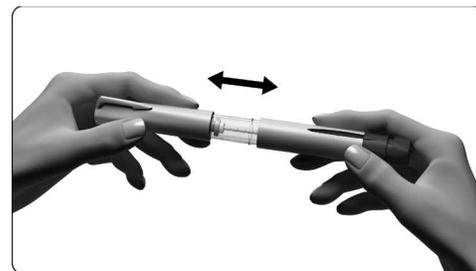


- On a clean surface, e.g., clean table or kitchen surface, lay out everything you will need:
 - OVIDREL Pen
 - One removable injection needle
 - Alcohol wipes (not supplied with product)
 - Sharps disposal container (not supplied with product)
- Verify the **expiration date** on the pen label. Do not use expired medication.



2. Getting your OVIDREL Pen ready for injection

- Take off the pen cap.
- Wipe the end of the threaded tip (containing the rubber center) using an alcohol wipe.
- Look carefully at the reservoir holder. Check that the reservoir holder is not cracked and that the solution is clear and does not contain particles. If the reservoir holder is cracked or if the solution is discoloured or cloudy, obtain a new pen.
- Verify that the Dose Display is set to “0”.



- Prepare your needle for injection:
- Get a new needle – only use the ‘single use’ needles supplied for the OVIDREL Pen.
- Hold the outer needle cap firmly.
- Check that the peel-off seal on the outer needle cap is not damaged or loose. If it is damaged or loose, do not use the needle and get another. Throw away the unused needle with the outer needle cap still on, in a sharps container.



- Remove peel-off seal.

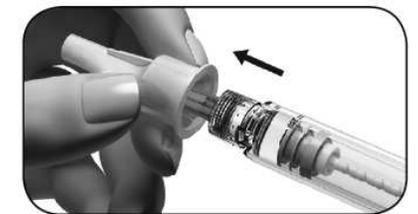


3. Attach the needle

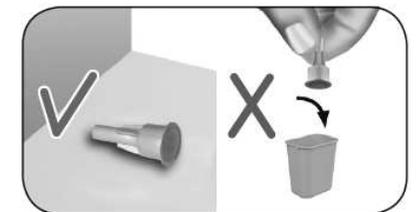
- Press the threaded tip of the OVIDREL Pen into the outer needle cap and twist it clockwise until you feel a light resistance.
- Important Note: Do not attach the needle too tightly; the needle could be difficult to remove after the injection.



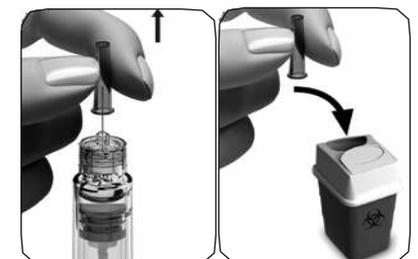
- Remove the outer needle cap by pulling it straight off.



- Put it aside for later use.
- Do not throw away the outer needle cap; you will need it for removing the needle from the pen.

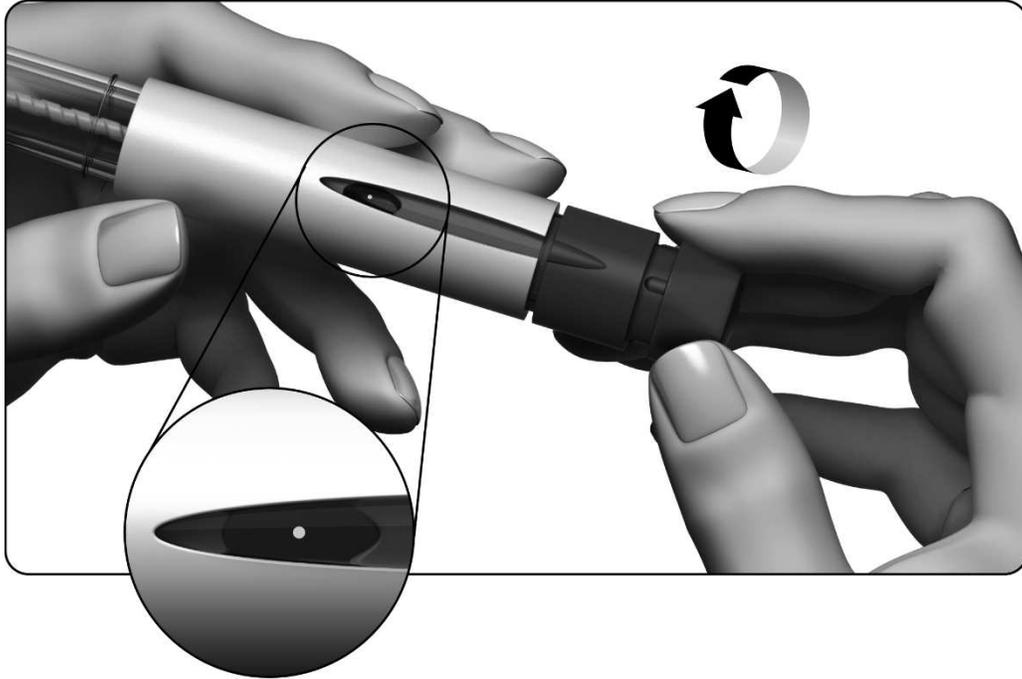


- Hold the OVIDREL Pen with the needle pointing upward.
- Carefully remove and discard the inner green shield.

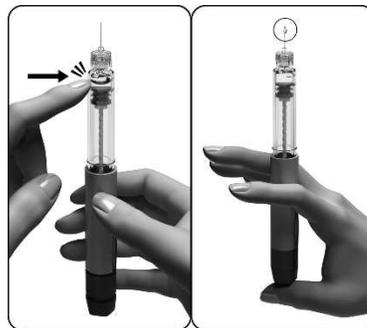


- Look closely at the tip of the needle for tiny drop(s) of fluid. If you see a tiny drop(s) of fluid, proceed to Section 4: **Setting the dose to 250**.

Caution: If you do not see a tiny drop(s) of fluid at or near the needle tip, you must perform the steps below:

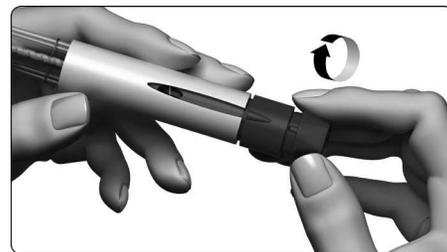


1. Gently turn the Dose Setting Knob clockwise until you see a dot (●) in the Dose Display. If you pass this position, simply turn the Dose Setting Knob back to the dot (●).
2. Hold the pen with the needle pointing upwards.
3. Tap the reservoir holder gently.
4. Press the Dose Setting Knob as far as it will go. A tiny drop of liquid will appear at the top of the needle; this shows that your prefilled pen is ready for injection.
5. If you do not see any liquid, you may try a second time (you may do this a maximum of two times) starting from Step 1 of this section “If you do not see a tiny drop of fluid at or near the needle tip” above.

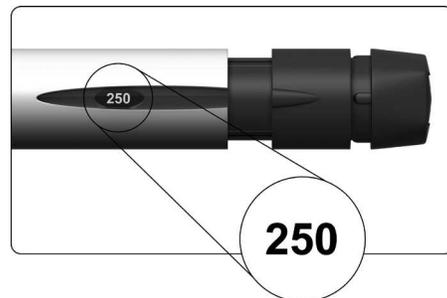


4. Setting the dose to 250

- Gently turn the Dose Setting Knob clockwise. The Dose Display will show a straight line and you have to keep turning until you can read the number “250”.
- Do not push or pull the dose setting button while you turn it.



- If not already done while removing air, carefully remove the inner needle shield.
- Check that the Dose Display shows “250” before you move on to the next step.



5. Injecting your dose

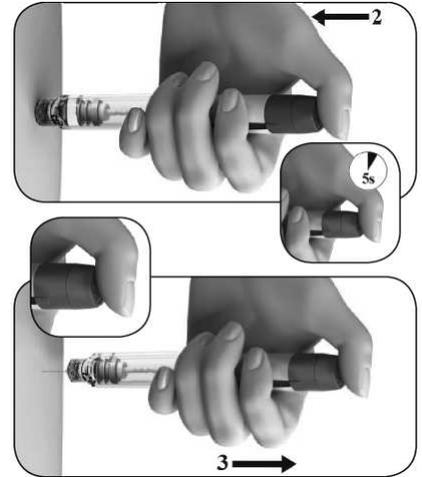
- Choose the place to give the injection where your doctor or nurse has told you – usually on your upper thighs or abdomen.



- Clean the skin by wiping the area with an alcohol wipe. Allow the site to dry.
- Lay the used side of the alcohol wipe to the side.
- Verify once more that the Dose Display reads “250”. If it does not, you must adjust it (see step **4. Setting your dose to 250**).
- Inject the dose as you were told to by your doctor or nurse.
- Holding the pen in one hand, use your other hand to gently squeeze the skin together to make a raised area at the injection site. Slowly push the needle into the skin (1).
- Insert the needle at a 90° angle into the skin. You might bend the needle if you do not insert it at a 90° angle.
- Press the Dose Setting Knob down as far as it will go and hold it to complete the full injection.

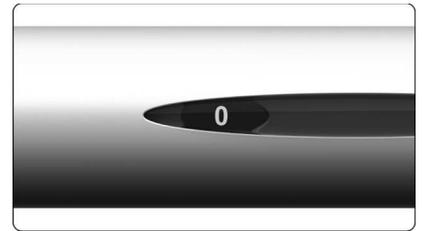


- Hold the Dose Setting Knob down for a minimum of 5 seconds to ensure you inject the full dose (2). **Do not release the Dose Setting Knob until you remove the needle from your skin.**
- Remove the needle from your skin (3), release the Dose Setting Knob.
- The dose number shown in the Dose Display will turn back to “0”. This shows that the complete dose was delivered.
- Use the clean side of the alcohol wipe to gently apply pressure where you have just injected.



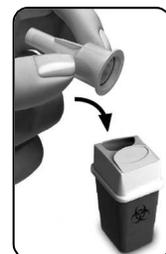
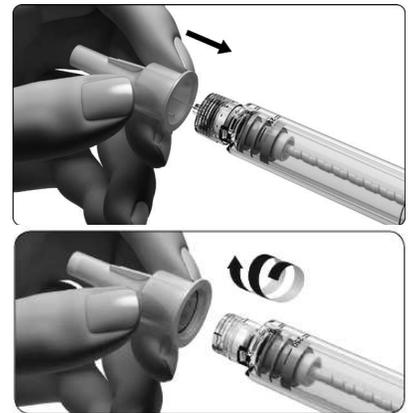
6. After the injection

- Verify you have given a complete injection.
- Check that the Dose Display reads “0”.
- This confirms that your dose has been fully delivered. **Do not attempt to inject a second time.**
- **In case the Dose Display doesn’t show “0”, please contact your doctor.**



7. Removing the needle after injection

- Hold the pen firmly by the reservoir holder.
- Carefully put the outer needle cap back onto the needle. Be careful not to prick yourself with the needle.
- Grip the outer needle cap and unscrew the needle by turning the cap counter clockwise. Dispose of the used needle safely.



8. Disposal

- Use the needle and pen only once.
- Discard the pen.
- When the pen is empty, ask your pharmacist how to dispose of it.
Important note: Medicines should not be disposed of via wastewater or household waste.

Storing the pre-filled syringe and pre-filled pen

- Refer to the date indicated on the labels for expiry date. Do not use after expiry date.
- Do not freeze. Protect from light. Store in original package.
- Do not use the OVIDREL pre-filled syringe or pre-filled pen if the solution contains particles or is not clear.
- OVIDREL in pre-filled pens are to be stored at 2-8°C (in a refrigerator).
- OVIDREL in pre-filled syringes are to be stored at 2-8°C (in a refrigerator). The patient may store the pre-filled syringe at 25°C (room temperature) for up to 30 days, however after this time the pre-filled syringe should be discarded.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

QUESTIONS AND ANSWERS

Q. What is OVIDREL (choriogonadotropin alfa)?

A. OVIDREL is the only recombinant human chorionic gonadotrophin (r-hCG). Its generic name is choriogonadotropin alfa. It is produced as a solution in a pre-filled syringe or a pre-filled pen that is intended for subcutaneous injection. OVIDREL ensures that you are receiving the highest purity hCG on the market. Subcutaneous injections offer the advantage of being convenient and easy to self-administer.

Q. What does OVIDREL do?

A. OVIDREL is used to trigger ovulation in infertile women with ovarian dysfunction.

Q. What is hCG?

A. Human chorionic gonadotrophin, or hCG, is a hormone that is involved in reproduction in women. It is found in the urine of pregnant women and is produced by the placenta.

Q. Who can take OVIDREL?

A. OVIDREL is indicated for women following the stimulation phase of infertility treatment.

Q. What is the amount of OVIDREL that must be injected?

A. 250 µg in a pre-filled pen or 250 µg in 0.5 ml for the ready to use solution packaged in a pre-filled syringe.

In case of a drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Q. What are the side effects associated with the use of OVIDREL?

A. As with other hCG preparations, side effects can occur with the use of OVIDREL: discomfort at the injection site, stomach pain, nausea, and vomiting have been reported. Ask your fertility team to discuss the possible side effects with you. As with all medications, it is important to report any physical changes and all symptoms to your healthcare professional.

Q. What risk is there of developing OHSS while on OVIDREL?

A. Contact your doctor if you experience severe pain or bloating in the stomach or pelvic area, severe upset stomach, vomiting, or weight gain, as these are symptoms of a medical event called Ovarian Hyperstimulation Syndrome (OHSS). OHSS occurs infrequently (usually less than 3% incidence). However, because OHSS can progress rapidly to a serious medical event, OVIDREL should be stopped at the first signs of OHSS.

Q. Is OVIDREL associated with multiple births?

A. Reports of multiple births have been associated with fertility treatments. You should discuss the potential risk of multiple births with your doctor before beginning treatment.

Q. Is OVIDREL associated with congenital birth defects?

A. There is no evidence to establish an association between the administration of OVIDREL to female patients and the occurrence of congenital anomalies in their offspring. The data supporting this position is derived from the conclusions of clinical trials, as well as from post-marketing

information where no cases of congenital anomalies have been reported since the introduction of OVIDREL to the market. Moreover, based on large epidemiological studies published in the literature, the rate of major or minor congenital anomalies following assisted reproductive technology procedures is consistent with that found in the unassisted population. It must be noted that these epidemiological studies relate to clinical trials carried out with urinary drugs. There is, however, no ground to suspect that, with regards to this particular risk, the recombinant product would be different from similar drugs of urinary origin.

Q. Can I take OVIDREL with other medications?

A. Please inform your doctor and pharmacist if you are taking or have taken any other medications, even those not requiring a prescription.

While the information contained in the "Information for the Patient" section provides important information about OVIDREL, it does not contain all the possible uses, actions, precautions, side effects, warnings, contraindications, and interactions of this medication. For more detailed information, please be sure to consult the package insert for this product and to discuss any questions you may have with your physician prior to beginning therapy.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.