

Package leaflet: Information for the user

Ovitrelle 250 micrograms solution for injection in pre-filled pen choriogonadotropin alfa

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ovitrelle is and what it is used for
2. What do you need to know before you use Ovitrelle
3. How to use Ovitrelle
4. Possible side effects
5. How to store Ovitrelle
6. Contents of the pack and other information

1. What Ovitrelle is and what it is used for

What Ovitrelle is

Ovitrelle contains a medicine called ‘choriogonadotropin alfa’, made in a laboratory by a special recombinant DNA technique. Choriogonadotropin alfa is similar to a hormone found naturally in your body called ‘chorionic gonadotropin’, which is involved in reproduction and fertility.

What Ovitrelle is used for

Ovitrelle is used together with other medicines:

- To help develop and ripen several follicles (each containing an egg) in women undergoing assisted reproductive technologies (procedure that may help you to become pregnant) such as ‘*in vitro* fertilisation’. Other medicines will be given first to bring about the growth of several follicles.
- To help release an egg from the ovary (ovulation induction) in women who cannot produce eggs (‘anovulation’), or women who produce too few eggs (‘oligo-ovulation’). Other medicines will be given first to develop and ripen the follicles.

2. What do you need to know before you use Ovitrelle

Do not use Ovitrelle

- if you are allergic to choriogonadotropin alfa or any of the other ingredients of this medicine (listed in section 6).
- if you have a tumour in your hypothalamus or pituitary gland (both are parts of the brain).
- if you have large ovaries or sacs of fluid within the ovaries (ovarian cysts) of unknown origin.
- if you have unexplained vaginal bleeding.
- if you have cancer of your ovaries, womb or breast.
- if you have severe inflammation of your veins or blood clotting in your veins (active thromboembolic disorders).

- if you have any condition that usually makes a normal pregnancy impossible, such as menopause or early menopause (ovarian failure), or malformations of sexual organs.

Do not use Ovitrelle if any of the above applies to you. If you are not sure, talk to your doctor before using this medicine.

Warnings and precautions

Before the treatment is started, your and your partner's fertility should be evaluated by a doctor experienced in the treatment of fertility problems.

Ovarian hyperstimulation syndrome (OHSS)

This medicine may increase your risk of developing OHSS. This is when your follicles develop too much and become large cysts.

If you get lower abdominal pain, gain any weight rapidly, feel sick or are vomiting, or have difficulty in breathing, do not give yourself the Ovitrelle injection and talk to your doctor straight away (see section 4). If you are developing OHSS, you may be told not to have sex or to use a barrier contraceptive method for at least four days.

The risk of OHSS is reduced if the usual dose of Ovitrelle is used, and if you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

Multiple pregnancy and/or birth defects

When using Ovitrelle, you have a higher risk of being pregnant with more than one child at the same time ('multiple pregnancy', usually twins) than if you conceived naturally. Multiple pregnancy may lead to medical complications for you and your babies. When undergoing assisted reproductive technologies, the risk of having a multiple pregnancy is related to your age, the quality and the number of fertilised eggs or embryos placed inside you. Multiple pregnancies and specific characteristics of couples with fertility problems (e.g. age) may also be associated with an increased chance of birth defects.

The risk of multiple pregnancy is reduced if you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

Ectopic pregnancy

Pregnancy outside of the womb (an ectopic pregnancy) may occur in women with damaged fallopian tubes (the tubes which carry the egg from the ovary to the womb). Therefore, your doctor should perform an early ultrasound examination to rule out the possibility of pregnancy outside the womb.

Miscarriage

When undergoing assisted reproductive technologies or stimulation of your ovaries to produce eggs, you are more likely to have a miscarriage than the average woman.

Blood clotting problems (thromboembolic events)

Talk to your doctor before using Ovitrelle if you or a member of your family have ever had blood clots in the leg or in the lung, or a heart attack or stroke. You may be at a higher risk of serious blood clots or existing clots might become worse with Ovitrelle treatment.

Tumours of sexual organs

There have been reports of tumours in the ovaries and other sex organs, both benign and malignant, in women who have undergone multiple regimens for infertility treatment.

Pregnancy tests

If you do a pregnancy test with serum or urine after use of Ovitrelle, and up to ten days later, it may happen that you get a false positive test result. If you are not sure, talk to your doctor.

Children and adolescents

Ovitrelle is not for use in children and adolescents.

Other medicines and Ovitrelle

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not use Ovitrelle if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines

It is not expected that Ovitrelle will affect your ability to drive and use machines.

Ovitrelle contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Ovitrelle

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

- The recommended dose is 1 pre-filled pen (250 micrograms/0.5 mL) given as a single injection.
- Your doctor will explain to you exactly when to give the injection.

Using this medicine

- If you administer Ovitrelle to yourself, please carefully read and follow the separate “Instructions for use” provided in the carton.
- Ovitrelle is intended to be given by injection under the skin (subcutaneously).
- Each pre-filled pen is for single use only.
- Your doctor or nurse will show you how to use the Ovitrelle pre-filled pen to inject the medicine.
- Inject Ovitrelle as your doctor or nurse taught you.
- After the injection, dispose of the used needle safely, and discard the pen.

If you use more Ovitrelle than you should

The effects of an overdose of Ovitrelle are unknown, nevertheless there is a possibility that ovarian hyperstimulation syndrome (OHSS) may occur, which is further described in section 4.

If you forget to use Ovitrelle

If you forget to use Ovitrelle, please talk to your doctor as soon as you notice.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Ovitrelle and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Allergic reactions such as rash, fast or uneven pulse, swelling of your tongue and throat, sneezing, wheezing, or serious breathing difficulty are very rare (may affect up to 1 in 10,000 people).
- Lower abdominal pain, abdominal distension or abdominal discomfort together with nausea (feeling sick) or vomiting may be the symptoms of ovarian hyperstimulation syndrome (OHSS). This may indicate that the ovaries over-reacted to the treatment and that large ovarian cysts developed (see also in section 2. under “Ovarian hyperstimulation syndrome”). This event is common (may affect up to 1 in 10 people).
- The OHSS may become severe with clearly enlarged ovaries, decreased urine production, weight gain, difficulty in breathing and possible fluid accumulation in your stomach or chest. This event is uncommon (may affect up to 1 in 100 people).
- Serious blood clotting complications (thromboembolic events) sometimes independent of OHSS may be found very rarely. This could cause chest pain, breathlessness, stroke or heart attack (see also in section 2. under “Blood clotting problems”).

Other side effects

Common (may affect up to 1 in 10 people)

- Headache.
- Local reactions at the injection site, such as pain, redness or swelling.

Uncommon (may affect up to 1 in 100 people)

- Diarrhoea.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ovitrelle

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C). Do not freeze.

Do not use Ovitrelle if you notice any signs of deterioration, if the liquid contains particles or is not clear.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ovitrelle contains

- The active substance is choriogonadotropin alfa, produced by recombinant DNA technology.
- Each pre-filled pen contains 250 micrograms choriogonadotropin alfa in 0.5 mL (equivalent to approximately 6,500 International Units, IU).
- The other ingredients are mannitol, methionine disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate, poloxamer 188, phosphoric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Ovitrelle looks like and contents of the pack

- Ovitrelle comes as a clear, colourless to slightly yellow liquid for injection in a pre-filled pen.
- Each pen contains 0.5 mL of solution.
- It is supplied in packs of 1 pre-filled pen and 2 injection needles (one spare).

Marketing Authorisation Holder

Merck Serono Ltd, 5 New Square, Bedfont Lakes Business Park, Feltham, Middlesex, TW14 8HA, UK

Manufacturer

Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (Bari), Italy

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INSTRUCTIONS FOR USE

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

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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.

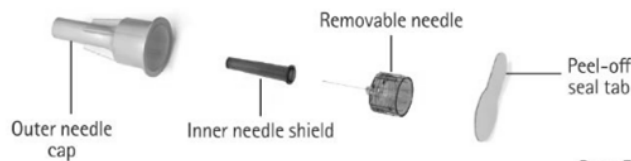
Do not freeze

Do not share the pen and/or needles with another person

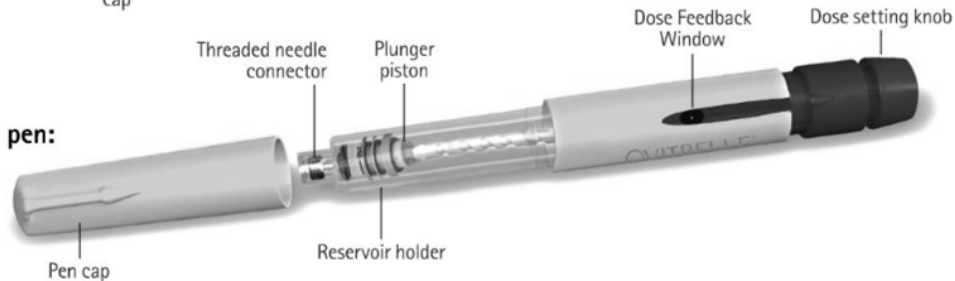
Do not use the Ovitrelle pre-filled pen if it has been dropped, or the pen is cracked or damaged as this can cause injury.

Get familiar with your Ovitrelle pre-filled pen

Your needle*:



Your 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



Fig. 3

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).

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.

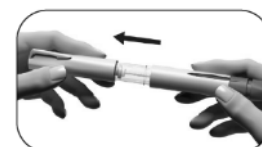


Fig. 4

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.

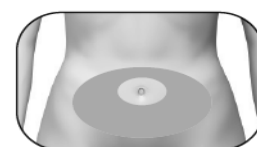


Fig. 5

Do not touch or cover the cleaned skin.

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).



Fig. 11

3.10 Carefully remove and discard the green inner shield (Figure 12).



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.

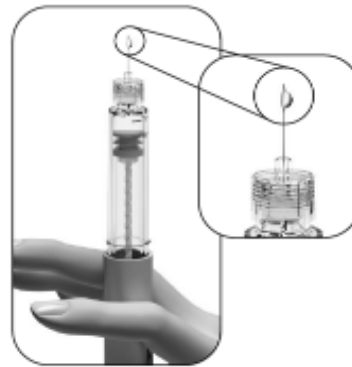


Fig. 13

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

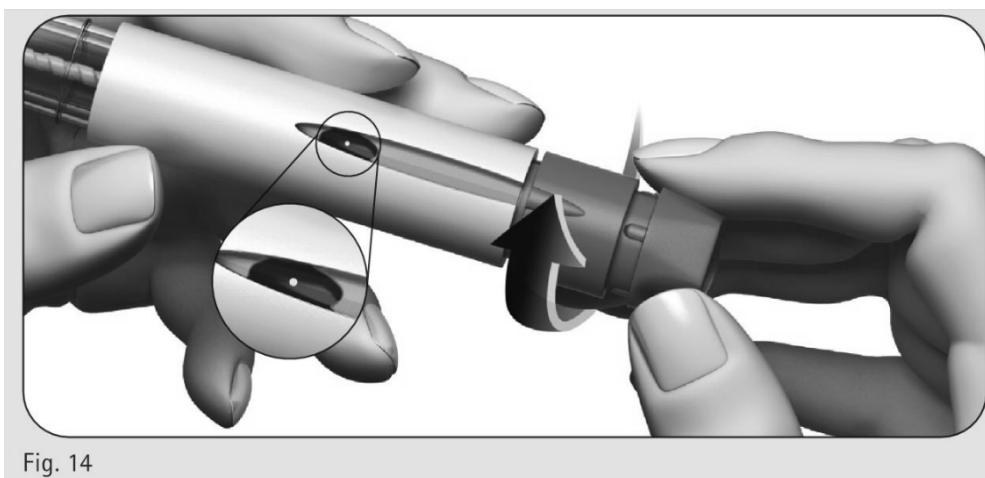


Fig. 14

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

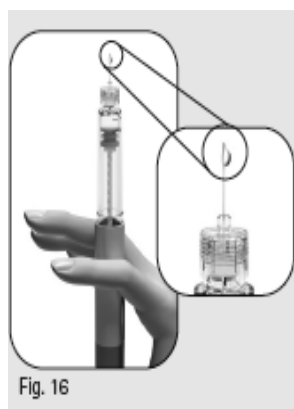


Fig. 16



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).

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.

Contact your healthcare provider if you need help.

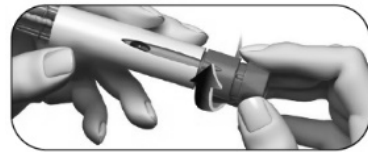


Fig. 18

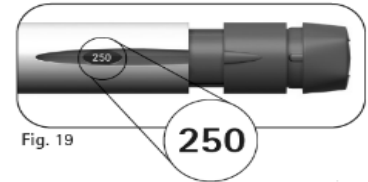


Fig. 19

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

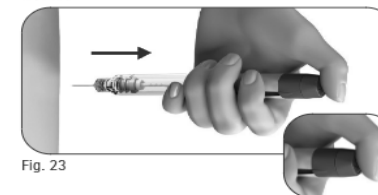


Fig. 23

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.

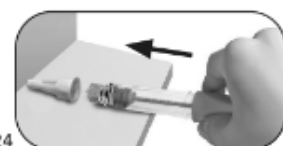


Fig. 24

- 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.

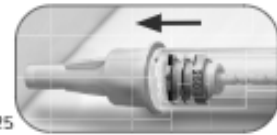


Fig. 25

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)

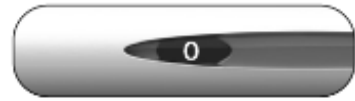


Fig. 28

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).

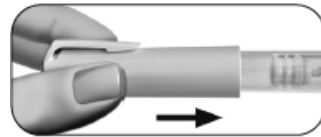


Fig. 29

- 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: April 2023