

Package leaflet: Information for the user

Ganirelix Gedeon Richter 0.25 mg/0.5 mL solution for injection in pre-filled syringe ganirelix

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ganirelix Gedeon Richter is and what it is used for
2. What you need to know before you use Ganirelix Gedeon Richter
3. How to use Ganirelix Gedeon Richter
4. Possible side effects
5. How to store Ganirelix Gedeon Richter
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1. What Ganirelix Gedeon Richter is and what it is used for

Ganirelix Gedeon Richter contains the active substance ganirelix and belongs to a group of medicines called “antigonadotropin-releasing hormones” which act against the actions of the natural gonadotropin-releasing hormone (GnRH). GnRH regulates the release of gonadotropins (luteinising hormone (LH) and follicle stimulating hormone (FSH)). Gonadotropins play an important role in human fertility and reproduction. In women, FSH is needed for the growth and development of follicles in the ovaries. Follicles are small round sacs that contain the egg cells. LH is needed to release the mature egg cells from the follicles and ovaries (i.e. ovulation). Ganirelix Gedeon Richter inhibits the action of GnRH, resulting in suppression of the release of especially LH.

Ganirelix Gedeon Richter is used for

In women undergoing assisted reproduction techniques, including *in vitro* fertilisation (IVF) and other methods, occasionally ovulation may occur too early causing a significant reduction in the chance of getting pregnant. Ganirelix Gedeon Richter is used to prevent the premature LH surge that might cause such a premature release of egg cells.

In clinical studies ganirelix was used with recombinant follicle stimulating hormone (FSH) or corifollitropin alfa, a follicle stimulant with a long duration of action.

2. What you need to know before you use Ganirelix Gedeon Richter

Do not use Ganirelix Gedeon Richter

- if you are allergic to ganirelix or any of the other ingredients of this medicine (listed in section 6);
- if you are hypersensitive to gonadotropin-releasing hormone (GnRH) or a GnRH analogue;
- if you have a moderate or severe kidney or liver disease;
- if you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ganirelix Gedeon Richter.

Allergic reactions

If you have an active allergic condition, please tell your doctor. Your doctor will decide, depending on the severity, if additional monitoring is required during treatment. Cases of allergic reactions have been reported, as early as with the first dose.

Allergic reactions, both generalised and local, including hives (urticaria), swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing and/or swallowing (angioedema and/or anaphylaxis) have been reported (see also section 4). If you have an allergic reaction, stop using Ganirelix Gedeon Richter and seek immediate medical assistance.

Ovarian hyperstimulation syndrome (OHSS)

During or following hormonal stimulation of the ovaries, ovarian hyperstimulation syndrome may develop. This syndrome is related to the stimulation procedure with gonadotropins. Please refer to the package leaflet of the gonadotropin-containing medicine prescribed for you.

Multiple births or birth defects

The incidence of congenital malformations after assisted reproduction techniques may be slightly higher than after spontaneous conceptions. This slightly higher incidence is thought to be related to characteristics of the patients undergoing fertility treatment (e.g. age of the woman, sperm characteristics) and to the higher incidence of multiple gestations after assisted reproduction techniques. The incidence of congenital malformations after assisted reproduction techniques using ganirelix is not different from that after using other GnRH analogues in the course of assisted reproduction techniques.

Pregnancy complications

There is a slightly increased risk of pregnancy outside of the uterus (an ectopic pregnancy) in women with damaged fallopian tubes.

Women weighing less than 50 kg or more than 90 kg

The efficacy and safety of ganirelix has not been established in women weighing less than 50 kg or more than 90 kg. Ask your doctor for further information.

Children and adolescents

There is no relevant use of Ganirelix Gedeon Richter in children or adolescents.

Other medicines and Ganirelix Gedeon Richter

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

Ganirelix Gedeon Richter should be used during controlled ovarian stimulation for assisted reproduction techniques (ART).

Do not use Ganirelix Gedeon Richter during pregnancy and breast-feeding.

Ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

The effects of Ganirelix Gedeon Richter on ability to drive and use machines have not been studied.

Ganirelix Gedeon Richter contains sodium

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

3. How to use Ganirelix Gedeon Richter

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

Ganirelix Gedeon Richter is used as part of the treatment for assisted reproduction techniques (ART) including *in vitro* fertilisation (IVF).

Ovarian stimulation with follicle stimulating hormone (FSH) or corifollitropin may start at day 2 or 3 of your period. Ganirelix Gedeon Richter (0.25 mg) should be injected into the fatty layer just under the skin once daily, starting on day 5 or day 6 of stimulation. Based on your ovarian response, your doctor may decide to start on another day.

Ganirelix Gedeon Richter and FSH should be administered approximately at the same time. However, these medicines should not be mixed and different injection sites are to be used.

Daily treatment with Ganirelix Gedeon Richter should be continued up to the day that sufficient follicles of adequate size are present. Final maturation of the egg cells in the follicles can be induced by administering human chorionic gonadotropin (hCG).

The time between two injections of Ganirelix Gedeon Richter as well as the time between the last injection of Ganirelix Gedeon Richter and hCG injection should not exceed 30 hours, as otherwise a premature ovulation (i.e. release of egg cells) may occur.

Therefore, when injecting Ganirelix Gedeon Richter in the morning treatment with Ganirelix Gedeon Richter should be continued throughout the gonadotropin treatment period including the day of triggering ovulation.

When injecting Ganirelix Gedeon Richter in the afternoon the last injection of Ganirelix Gedeon Richter should be given in the afternoon prior to the day of triggering ovulation.

Instructions for use

Before the administration of this medicine it is very important that you also carefully read and closely follow the detailed instructions for use provided at the end of this package leaflet.

Injection site

Ganirelix Gedeon Richter is supplied in pre-filled syringes and should be injected slowly, into the fatty layer just under the skin, preferably in the upper leg. Inspect the solution before use. Do not use if the solution contains particles or is not clear. You may notice air bubble(s) in the pre-filled syringe. This is expected, and removal of the air bubble(s) is not needed. If you administer the injections yourself or have it done by your partner, follow the instructions below and at the end of the Package leaflet carefully. Do not mix Ganirelix Gedeon Richter with any other medicines.

Preparing the injection site

Wash your hands thoroughly with soap and water. Swab the injection site with a disinfectant (for example alcohol) to remove any surface bacteria. Clean about 5 cm (two inches) around the point where the needle will go in and let the disinfectant dry for at least one minute before proceeding.

Inserting the needle

Remove needle shield. Pinch a fold of skin between index finger and thumb. Insert the needle at the base of the pinched-up skin at an angle of 45° to the skin surface. Vary the injection site with each injection.

Checking the correct needle position

Gently draw back the plunger to check if the needle is positioned correctly. Any blood drawn into the syringe means the needle tip has penetrated a blood vessel. If this happens, do not inject Ganirelix Gedeon Richter, but remove the syringe, cover the injection site with a swab containing disinfectant and apply pressure; bleeding should stop in a minute or two. Do not use this syringe and dispose of it properly. Start again with a new syringe.

Injecting the solution

Once the needle has been correctly placed, push the plunger down slowly and steadily, so the solution is correctly injected and the skin tissues are not damaged. Push the plunger down until the syringe is empty and wait for 5 seconds.

Removing the syringe

Pull the syringe out quickly and apply pressure to the site with a swab containing disinfectant. Use the pre-filled syringe only once.

If you use more Ganirelix Gedeon Richter than you should

Contact your doctor.

If you forget to use Ganirelix Gedeon Richter

If you realise that you forgot a dose, administer it as soon as possible.

Do not inject a double dose to make up for a forgotten dose.

If you are more than 6 hours late (so the time between two injections is longer than 30 hours) administer the dose as soon as possible **and** contact your doctor for further advice.

If you stop using Ganirelix Gedeon Richter

Do not stop using Ganirelix Gedeon Richter unless advised to by your doctor, as this may affect the outcome of your treatment.

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

4. Possible side effects

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

The chance of having a side effect is described by the following categories:

Very common (may affect more than 1 in 10 women)

- Local skin reactions at the site of injection (predominantly redness, with or without swelling). The local reaction normally disappears within 4 hours of administration.

Uncommon (may affect up to 1 in 100 women)

- Headache
- Nausea
- Feeling generally unwell (malaise)

Very rare (may affect up to 1 in 10,000 women)

- Allergic reactions have been observed, as early as with the first dose.
 - Rash
 - Facial swelling
 - Difficulty breathing (dyspnoea)
 - Swelling of face, lips, tongue, and/or throat that may cause difficulty in breathing and/or swallowing (angioedema and/or anaphylaxis)
 - Hives (urticaria)
- Worsening of a pre-existing rash (eczema) has been reported in one subject after the first ganirelix dose.

In addition, side effects are reported which are known to occur with controlled ovarian hyperstimulation treatment (e.g. abdominal pain, ovarian hyperstimulation syndrome (OHSS), ectopic pregnancy (when the embryo develops outside the womb) and miscarriage (see the package leaflet of the FSH-containing preparation you are treated with).

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:

for United Kingdom (Northern Ireland)

Yellow Card Scheme

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

for Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

for Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Ganirelix Gedeon Richter

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 on the carton after EXP. The expiry date refers to the last day of that month.

Do not freeze.

Store in the original package, in order to protect from light.

Inspect the syringe before use. Use only syringes with clear, particle-free solutions and from undamaged containers.

Each pre-filled syringe is only for a single use of injection.

Alcohol swabs, gauze pads and sharps container are needed for administration of this medicine but they are not provided in the pack.

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

6. Contents of the pack and other information

What Ganirelix Gedeon Richter contains

- The active substance is ganirelix (0.25 mg in 0.5 mL solution).
- The other ingredients are: glacial acetic acid, mannitol (E 421), water for injection. The pH (measurement of the acidity) may have been adjusted with sodium hydroxide (see section 2 “Ganirelix Gedeon Richter contains sodium”).

What Ganirelix Gedeon Richter looks like and contents of the pack

Ganirelix Gedeon Richter is a clear and colourless solution for injection (injection). The medicine is filled in a glass syringe with staked stainless steel needle, closed with a plunger stopper and supplied with a plunger rod. The injection needle is provided with a rigid needle shield.

Ganirelix Gedeon Richter is available in packs of 1 pre-filled syringe or 6 pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.

Gyömrői út 19-21.

1103 Budapest
Hungary

This leaflet was last revised in July 2022.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>

Instructions for use

HOW TO PREPARE AND ADMINISTER GANIRELIX GEDEON RICHTER IN PRE-FILLED SYRINGE

Before the administration of this medicine, carefully read these instructions and the package leaflet the whole way through.

These instructions will help you with how to give yourself or how your partner can give you an injection of Ganirelix Gedeon Richter. If you are not sure about administering the injection or you have any questions, please ask your doctor or pharmacist for help.

Do not mix Ganirelix Gedeon Richter with any other medicines.

Perform the injection at the same time each day.

Each pre-filled syringe contains one daily dose of ganirelix.

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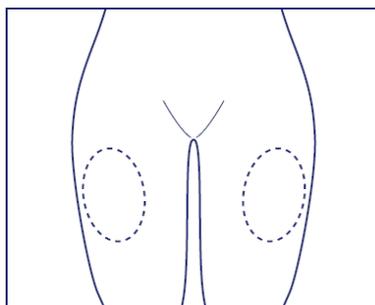
1. Preparing for the injection
2. Preparing the injection site
3. Injecting the medicine
4. After the injection

1. Preparing for the injection

- Wash your hands thoroughly with soap and water. It is important that your hands and the items you use are as clean as possible to avoid infections.
 - Find a clean area for the items you need for the injection, e.g. a clean table or similar horizontal surface.
 - Gather everything you need and lay them out into the clean area:
 - Swabs containing disinfectant (e.g. alcohol)
 - 1 pre-filled syringe containing the medicine
 - Do not hold the syringe by the plunger to avoid syringe disassembling.
 - Do not use this medicine after the expiry date which is stated on the label or on the carton after EXP. The expiry date refers to the last day of that month.
 - A puncture-resistant container (e.g. a plastic bottle with a wide enough opening) to dispose the used syringe safely.
 - Inspect the solution before use.
 - You may notice air bubble(s) in the pre-filled syringe. This is expected, and removal of the air bubble(s) is not needed.
 - Do not use the syringe if:
 - it is cracked or damaged, or
 - the needle shield has been removed or is not tightly attached or
 - a fluid leakage is visible or
 - the solution looks abnormal (it contains particles or it is not colourless).
- If any of these occurs, you should dispose the syringe safely into the sharps container and use another one.

2. Preparing the injection site

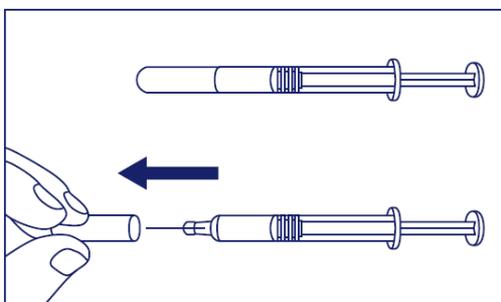
- Choose the injection site preferably in the upper leg. The injection site should be varied for each injection to prevent the damage of tissue under the skin.



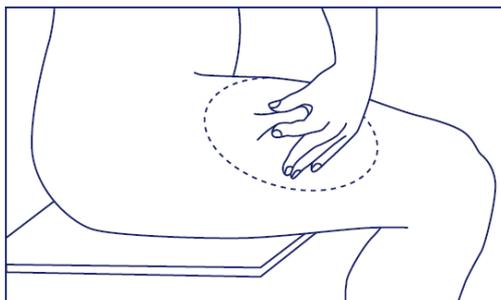
- Do not inject yourself in any area that is tender, damaged or bruised. Always choose an intact skin area for injecting the medicine.
- Do not inject through clothes.
- Administer Ganirelix Gedeon Richter and follicle stimulating hormone (FSH) approximately at the same time. However, these medicines should not be mixed, and different injection sites are to be used.
- Swab the injection site with a disinfectant (for example alcohol) at the chosen injection site to remove any surface bacteria. Clean an area of about 5 cm (two inches) in diameter around the point where the needle will go in and let the disinfectant dry for about 1 minute before proceeding.
- Do not touch the injection site again or blow on it before the injection.

3. Injecting the medicine

- You receive Ganirelix Gedeon Richter in pre-filled syringes with a staked needle, ready for administration without any further adjustments to the syringe.
- By grabbing the middle of the syringe body, remove 1 syringe from the pack.
- For injecting the medicine, pull off the needle shield from the syringe that is held horizontally and pointing away from you. Do not twist but pull the needle shield off.

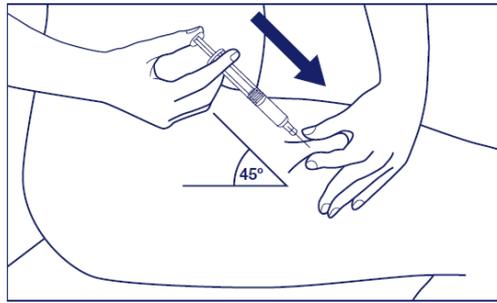


- When handling the syringe, do not touch the syringe tip or the needle with your fingers to avoid contamination.
- At the chosen and disinfected injection site, pinch up a fold of skin between your index finger and thumb.



- Administer Ganirelix Gedeon Richter subcutaneously, i.e. into the fatty layer just under the skin.
- Hold the syringe with your other hand so that you can place your thumb onto the plunger when

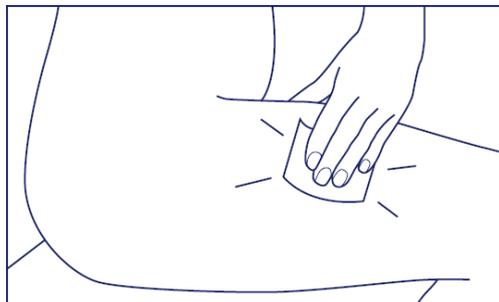
needed. Insert the needle completely with a quick, firm action into the middle of the pinched-up skin at an angle of 45° to the skin surface.



- Gently draw back the plunger to check if the needle is positioned correctly.
- Any blood drawn into the syringe means the needle tip has penetrated a blood vessel. If this happens, do not inject Ganirelix Gedeon Richter, but remove the syringe, cover the injection site with a swab containing disinfectant and apply pressure; bleeding should stop in a minute or two.
- Do not use this syringe and dispose of it properly and use a new syringe.
- Once the needle has been correctly placed, push the plunger down with your thumb slowly and steadily, so the solution is correctly injected and the skin tissues are not damaged.
- Push the plunger down until the syringe is empty.

4. After the injection

- Wait for 5 seconds (slowly count to 5), then let go of the skin you are pinching.
- Pull the syringe out quickly from your skin and apply pressure to the site with a swab containing disinfectant.



- Do not rub your skin after the injection.
- Use each pre-filled syringe only once.
- Do not recap the needle to avoid needle stick injury.
- Discard the used syringe safely in the puncture-resistant container immediately, and return to the pharmacy for a correct disposal. Ask your pharmacist how to dispose of medicines you no longer use.