

Package leaflet: Information for the patient

Vyvgart 1 000 mg solution for injection efgartigimod alfa

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Vyvgart is and what it is used for

What Vyvgart is

Vyvgart contains the active substance efgartigimod alfa. Efgartigimod alfa binds to and blocks a protein in the body called neonatal Fc receptor (FcRn). By blocking FcRn, efgartigimod alfa decreases the level of immunoglobulin G (IgG) autoantibodies which are proteins of the immune system that attack parts of a person's own body by mistake.

What Vyvgart is used for

Vyvgart is used together with standard therapy to treat adults with generalised Myasthenia Gravis (gMG), an autoimmune disease that causes muscle weakness. gMG can affect multiple muscle groups throughout the body. The condition can also lead to shortness of breath, extreme fatigue and difficulties swallowing.

In patients with gMG, IgG autoantibodies attack and damage proteins on nerves called acetylcholine receptors. Because of this damage, the nerves are not able to make the muscles contract as well as normal, leading to muscle weakness and difficulty moving. By binding to the FcRn protein and reducing autoantibody levels, Vyvgart can improve the ability of muscles to contract and reduce the symptoms of the disease and their impact on daily activities.

2. What you need to know before you use Vyvgart

Do not use Vyvgart

- if you are allergic to efgartigimod alfa or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Vyvgart.

MGFA class V

Your doctor may not prescribe this medicine if you are on a ventilator due to gMG muscle weakness (myasthenic crisis).

Infections

Vyvgart treatment may reduce your natural resistance to infections. Therefore, before starting Vyvgart, inform your doctor if you have any infections.

Injection reactions and allergic reactions

Vyvgart contains a protein that can cause reactions such as rash or itching in some people. Vyvgart may cause anaphylactic reaction (a serious allergic reaction). If you experience allergic reactions such as swelling of the face, lips, throat or tongue which makes it difficult to swallow or breathe, shortness of breath, feeling of loss of consciousness, or skin rash during or after the injection, then tell your doctor immediately.

Immunisations (vaccinations)

Please inform your doctor if you have received a vaccine in the last 4 weeks, or if you plan to be vaccinated in the near future.

Children and adolescents

Do not give this medicine to children below 18 years of age because the safety and efficacy of Vyvgart have not been established in this population.

Elderly

There are no special precautions needed for the treatment of patients who are older than 65 years of age.

Other medicines and Vyvgart

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Vyvgart is not expected to influence the ability to drive or use machines.

Vyvgart contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially "sodium-free".

3. How to use Vyvgart

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

What dose of Vyvgart you will receive and how often

The recommended dose is 1 000 mg given in cycles of one injection per week for 4 weeks. Your doctor will determine when further treatment cycles are needed.

If you are already on intravenous Vyvgart treatment and wish to transition to Vyvgart subcutaneous, you should receive the subcutaneous injection instead of your intravenous infusion at the start of the next treatment cycle.

Injecting Vyvgart

Vyvgart is given by injection under the skin (*subcutaneously*). You and your doctor should decide if, after adequate training, you or your caregiver may inject Vyvgart. The first self-injection should be carried out in front of your healthcare provider. It is important not to try to inject Vyvgart before being trained by a healthcare professional.

If you or your caregiver inject Vyvgart, you or your caregiver must carefully read and follow the Instructions for administration at the end of this leaflet (see “**Important instructions for use**”). Talk to your doctor, pharmacist or nurse if you have any questions about giving yourself an injection.

If you use more Vyvgart than you should

Because Vyvgart is given in one single-use vial, it is unlikely that you will receive too much. However, if you are worried, please contact your doctor, pharmacist or nurse for advice.

If you miss a dose of or forget an appointment to receive Vyvgart

Keep track of your next dose. It is important to use Vyvgart exactly as prescribed by your doctor.

- If you miss your dose within three days of when you are supposed to take it, take your dose as soon as you remember and then follow your original dosing schedule.
- If you miss your dose by more than three days, ask your doctor when to take your next dose.
- If you forget an appointment, please contact your doctor immediately for advice.

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

If you stop using Vyvgart

Interrupting or stopping treatment with Vyvgart may cause your gMG symptoms to come back. Please speak to your doctor before stopping Vyvgart. Your doctor will discuss the possible side effects and risks with you. Your doctor will also want to monitor you closely.

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. Your doctor will discuss the possible side effects with you and explain the risks and benefits of Vyvgart with you prior to treatment.

Tell your doctor straight away if you notice:

Signs of a serious allergic reaction (anaphylactic reaction) such as swelling of the face, lips, throat or tongue which makes it difficult to swallow or breathe, shortness of breath, feeling of loss of consciousness, or skin rash during or after the injection.

If you are not sure what the side effects below are, ask your doctor to explain them to you.

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

- nose and throat (upper respiratory tract) infections
- reactions where the injection was given, which may include redness, itching, pain. These injection site reactions are usually mild to moderate and usually occur within a day after the injection.

Common (may affect up to 1 in 10 people)

- pain or a burning sensation during urination, which may be a sign of a urinary tract infection
- inflammation of the airways in the lungs (bronchitis)
- muscle pain (myalgia).

Not known (frequency cannot be estimated from the available data)

- allergic reactions during or after injection

- swelling of the face, lips, throat, or tongue which makes it difficult to swallow or breathe, shortness of breath
- pale skin, a weak and rapid pulse, or a feeling of loss of consciousness
- sudden rash, itching, or hives.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MRHA 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 Vyvgart

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

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

If needed, unopened vials may be stored at room temperature (up to 30 °C) for up to 3 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside cold storage and at room temperature should not exceed 3 days.

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

Do not use this medicine if you notice visible particles.

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 Vyvgart contains

- The active substance is efgartigimod alfa. Each vial contains 1 000 mg efgartigimod alfa in 5.6 mL. Each mL contains 180 mg of efgartigimod alfa.
- The other ingredients are: Recombinant human hyaluronidase (rHuPH20), L-histidine, L-histidine hydrochloride monohydrate, L-methionine, Polysorbate 20, Sodium chloride, sucrose, Water for injections. See section 2 “Vyvgart contains sodium”.

What Vyvgart looks like and contents of the pack

Vyvgart is a ready to use, slightly yellow, clear to slightly cloudy solution, supplied as a solution for subcutaneous injection.

Marketing Authorisation Holder and Manufacturer

argenx BV
 Industriepark-Zwijnaarde 7
 9052 Gent
 Belgium
 e-mail: ukmedinfo@argenx.com

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: Tel. +44 (0) 20 4532 4016

This leaflet was last revised in September 2023.

Important instructions for use

Vyvgart 1 000 mg solution for injection
efgartigimod alfa
Subcutaneous use

Be sure to read and understand these instructions for use before injecting Vyvgart. If you or your caregiver are willing to administer Vyvgart, you will get training on how to inject Vyvgart by your healthcare professional. Your healthcare professional should show you or your caregiver how to prepare and inject Vyvgart properly before using it for the first time. A demonstration of proper self-administration under supervision of healthcare professional is considered necessary. It is important that you do not try to inject the medicinal product until you have been trained and you or your caregiver are sure that you understand how to use Vyvgart. Ask your healthcare professional if you have any questions.

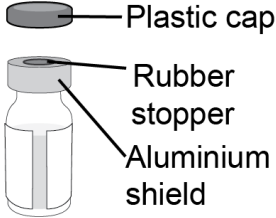

Important information you need to know before injecting Vyvgart subcutaneous

- **For subcutaneous use only.**
- The vial is for single use only. **Do not** save vials, even if they are not empty.
- **Do not** use a vial if you see unusual cloudiness or visible particles. The medicine should appear slightly yellow, clear to slightly cloudy.
- **Do not** shake the vial during handling.
- **Do not** use damaged vials or vials missing a protective cap. Report and return damaged or uncapped vials to the pharmacy.

Storing Vyvgart


- Store in a refrigerator (2 °C - 8 °C).
- **Do not** freeze.
- If needed, unopened vials may be stored at room temperature (up to 30 °C) for up to 3 days. After storage at room temperature unopened vials may be returned to the refrigerator. The total amount of time outside cold storage and at room temperature should not exceed 3 days.
- Store in the original package in order to protect from light.
- Keep this medicine out of the sight and reach of children.

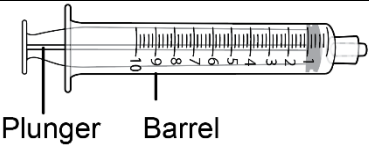
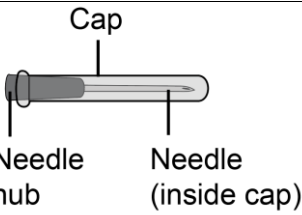
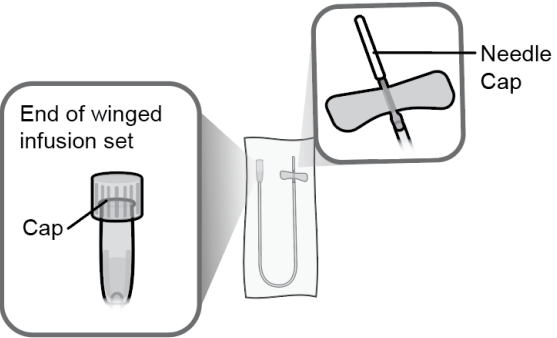


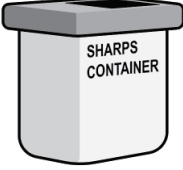
Package contents

1 vial containing Vyvgart	
Vyvgart package leaflet and instructions for use	

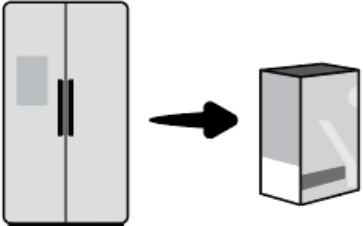
Additional supplies not included

Store additional supplies at room temperature in a dry location

Alcohol swabs	
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Syringe 10 mL	
Transfer needle 18-gauge, 50 mm length	
Winged infusion set 25-gauge, 30 cm tubing, maximum priming volume of 0.4 mL	
Sterile gauze	
Adhesive bandage	
Sharps container	

Preparing the supplies

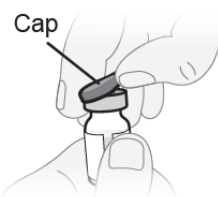
<p>Step 1 Remove vial carton from the refrigerator.</p>	
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Preparing the syringe

Step 6

Remove the plastic flip-off protective cap from the vial.

The aluminium shield should remain in place.



Step 7

Clean the rubber stopper with a new alcohol swab.

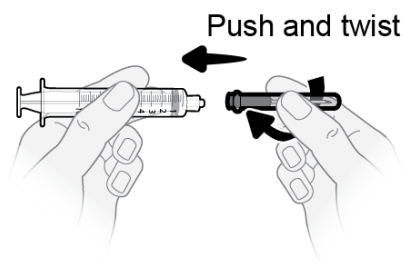
Allow to air dry naturally for at least 30 seconds. **Do not** blow on the rubber stopper.



Step 8

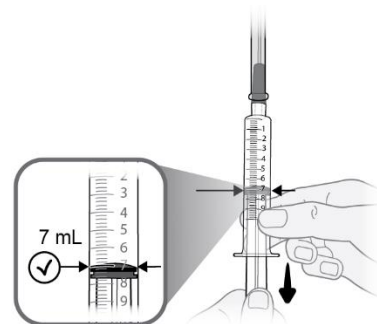
Unwrap the syringe and transfer needle. Push the transfer needle onto the syringe and twist it clockwise until the needle is firmly connected to the syringe.

Do not touch the tip of the syringe or the bottom of the needle to avoid germs and infection risk.



Step 9

Slowly pull back on the plunger and draw air into the syringe up to 7 mL.



Step 10

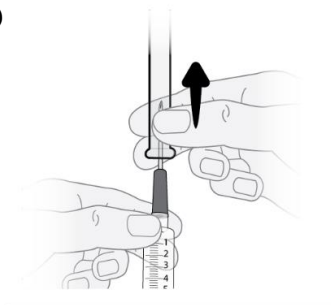
10a. Hold the syringe at the needle hub where the syringe is connected to the needle.

10b. Grip the transfer needle cap and carefully pull the needle cap straight off, away from your body.

10c. Place the transfer needle cap down on a clean, flat surface.

- **Do not** throw the cap away. You will need to recap and remove the transfer needle after use. Keep the needle sterile:
- **Do not** touch the needle or needle tip.
- **Do not** place it on a surface after the needle cap has been removed.

10b)



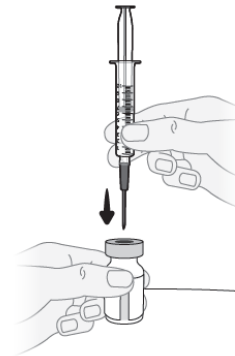
10c)



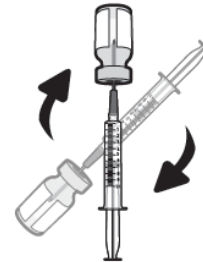
Step 11

Keep the vial upright on a flat surface and insert the transfer needle through the centre of the disinfected rubber stopper.

Do not puncture the vial's rubber stopper more than one time to avoid leaking.

**Step 12**

Turn the vial upside down while keeping transfer needle in the vial.

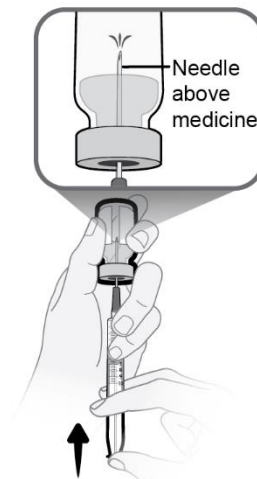
**Step 13**

13a. Make sure the transfer needle in the vial points upwards with the needle tip above the medicine solution.

13b. Gently push the plunger to inject all the air from the syringe into the empty space above the medicine solution in the vial.

13c. Keep your finger pressed down on the syringe plunger.

Do not inject air into the medicine solution as this could create air bubbles or foam.

**Step 14**

Fill the syringe, as follows:

14a. Keep your finger pressed on the syringe plunger and slide the transfer needle tip into the medicine solution in the neck of the vial (close to the vial cap) so that the needle tip remains completely covered in the solution.

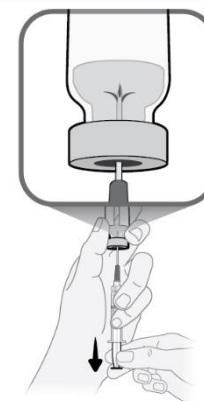
14b. Slowly pull back the plunger, keeping the transfer needle tip in the solution to avoid air bubbles and foam in the syringe.

Fill the syringe with the entire content of the vial.

14a)



14b)



Step 15

Remove large air bubbles, if present.

15a. Keep the transfer needle in the vial and check the syringe for large air bubbles.

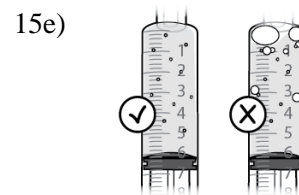
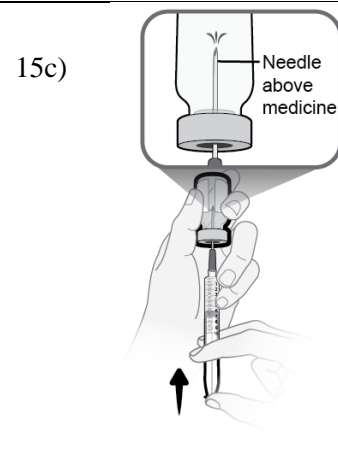
15b. Remove the large air bubbles by gently tapping the syringe barrel with your fingers until the air bubbles rise to the top of the syringe.

15c. Move the transfer needle tip above the medicine solution and slowly push the plunger up to push the air bubbles out of the syringe.

15d. To remove any remaining medicine solution from the vial, move the tip of the transfer needle into the solution again and slowly pull back the plunger until you have the full contents of the vial in the syringe.

15e. Repeat the steps above until you have removed the large air bubbles.

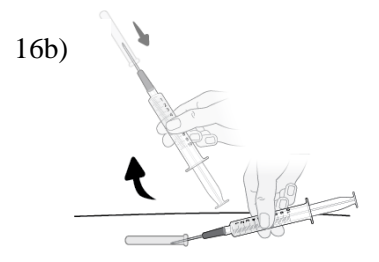
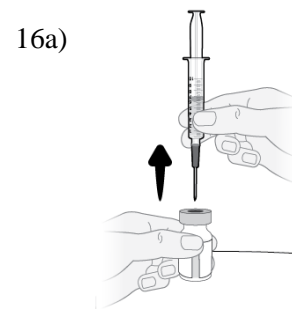
If you cannot remove all of the liquid from the vial, turn the vial upright to reach the remaining amount.

**Step 16**

16a. Turn the vial upright and remove the syringe and transfer needle from the vial.

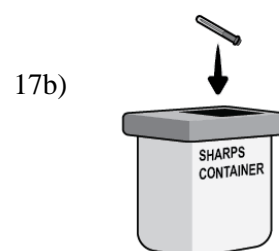
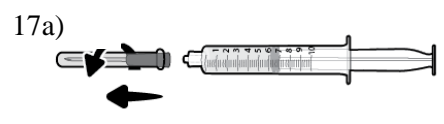
16b. Using one hand, slide the transfer needle into the cap and scoop upwards to cover the needle.

16c. After the transfer needle is covered, twist the transfer needle cap onto the syringe to fully attach it.

**Step 17**

17a. Gently pull and twist the transfer needle counter-clockwise to remove it from the syringe.

17b. Throw away (dispose of) the transfer needle in the sharps container.



Preparing to inject Vyvgart

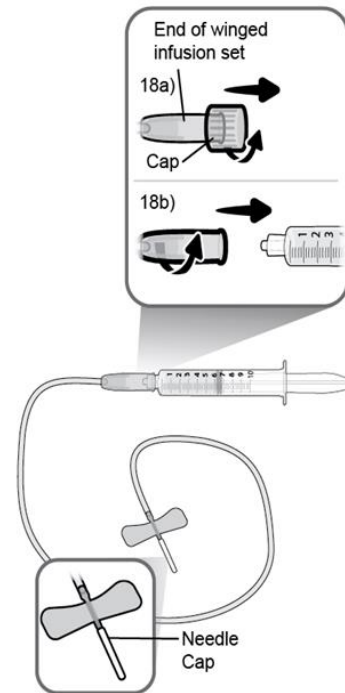
Step 18

18a. Remove the cap from the end of the winged infusion set.

18b. Gently push and twist the end of the winged infusion set clockwise onto the syringe until firmly connected.

The final syringe setup should look like the figure to the right.

- **Do not** touch the tip of the syringe.
- **Do not** remove the needle cap.

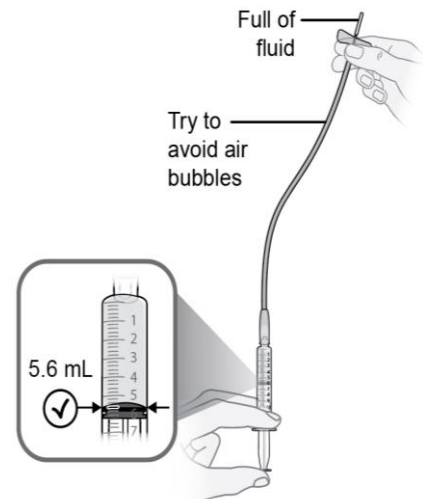


Step 19

19a. Fill the tubing of the winged infusion set by gently pressing the syringe plunger until the plunger is at the 5.6 mL mark. You should see some liquid at the end of the needle.

19b. Place the syringe and attached winged infusion set down on the clean, flat surface.

- **Do not** wipe off any excess medicine solution expelled from the infusion set while filling the tubing.



Step 20

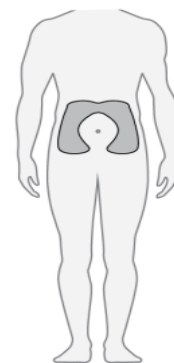
Choose an injection site

- on the abdomen (belly area) that is at least 5 cm away from the belly button

Choose a different injection site each time you inject (rotate the site) to decrease discomfort.

Note:

- **Do not** inject into areas where the skin is red, bruised, tender, hard, or into areas where there are moles or scars.



Step 21

Disinfect the injection site with a new alcohol swab. Use a circular motion and wipe from inside to outside.

Allow the site to air dry for at least 30 seconds.

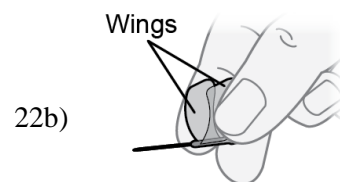
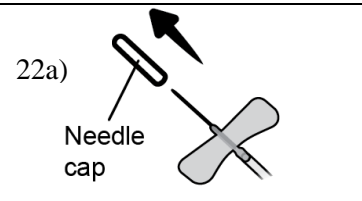
Do not touch the injection site after disinfecting.

**Injecting Vyvgart****Step 22**

22a. Remove the needle cap carefully from the winged infusion set.

22b. Fold the wings of the infusion set upwards and hold the wings between your thumb and index finger, with the needle below the wings.

Note:
To avoid infection, make sure the needle does not come into contact with anything prior to skin insertion.

**Step 23**

With your free hand, pinch a fold of skin around the disinfected injection site and lift upwards. Grab enough skin to create a “tent” for the needle to insert into.

Do not hold the skin too tight to avoid bruising.

**Step 24**

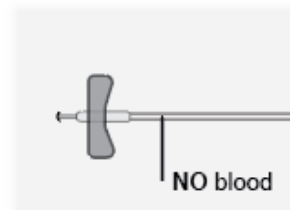
Insert the needle into the middle of the pinched skin area at an angle of about 45 degrees.

Note:
The needle should smoothly insert into the skin. If you feel resistance, you can pull the needle back slightly.

**Step 25**

Check the infusion set. Make sure there is no blood.

Important:
If you see blood, slightly pull back on the needle without removing the needle from the skin.



Step 26

Inject by pushing the plunger of the syringe with steady pressure until no medicine remains in the syringe. This corresponds to the injection of the recommended dose of 5.6 mL. The injection usually takes 30 to 90 seconds.

Note:

- If you experience discomfort, or if any of the medicine flows back into the infusion tubing, you can inject more slowly.
- There will be some fluid left in the infusion tubing that is not injected. This is normal and the remaining medicine can be thrown away.



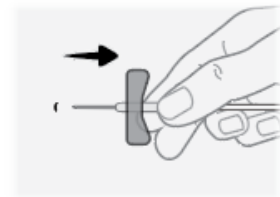
Step 27

27a. After all solution is injected, remove the needle from the skin.

27b. Cover the injection site with a sterile dressing, like an adhesive bandage.

Note:

If there is a small drop of blood after removing the needle, **do not** worry. This can happen if the needle nicks the skin during removal. Dab the blood with a sterile piece of gauze and apply gentle pressure. Further bleeding should not occur. Apply a sterile dressing to cover the site.



Disposing of Vyvgart

Step 28

Throw away (dispose of) the winged infusion set (with the attached needle and syringe) and the vial into the sharps container.

If you **do not** have an sharps disposal container, a household container can be used if it is:

- Made of heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps spilling out;
- Upright and stable;
- Leak-resistant;
- Appropriately labeled with a warning that hazardous waste is inside the container.

Dispose of the full container as instructed by your healthcare provider or pharmacist.

Note:

Always keep the sharps container out of the sight and reach of children.

