

Package leaflet: Information for the patient
Vyvgart 1 000 mg solution for injection
in pre-filled syringe
efgartigimod alfa

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▼ 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.

Vyvgart is also used to treat adults with chronic inflammatory demyelinating polyneuropathy (CIDP), a form of autoimmune disease. CIDP causes muscle weakness and/or numbness mainly in the legs and arms. Vyvgart can protect the nerves from being attacked 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 syringe, that is to say essentially "sodium-free".

Vyvgart contains polysorbate

This medicine contains 2.1 mg of polysorbate 80 in each syringe which is equivalent to 0.4 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

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

Generalized myasthenia gravis

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.

Chronic inflammatory demyelinating polyneuropathy

The recommended dose is 1 000 mg, one injection per week. Depending on how you respond to treatment, your doctor may change this to 1 injection every 2 weeks.

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 pre-filled syringe, 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 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)
- nausea.

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. You can also store the unopened pre-filled syringe at room temperature in the original carton up to 30 °C for a single period of up to 1 month after removing it from the refrigerator. Discard it if it has not been used within the 1 month period or by the expiry date, whichever happens first.

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 pre-filled syringe contains 1 000 mg efgartigimod alfa in 5.0 mL. Each mL contains 200 mg of efgartigimod alfa.
- The other ingredients are: Recombinant human hyaluronidase (rHuPH20), L-arginine hydrochloride, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, Polysorbate 80 (E433), 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 in a pre-filled syringe.

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 2025.

Important instructions for use

Vyvgart 1 000 mg solution for injection in pre-filled syringe
efgartigimod alfa
Subcutaneous use

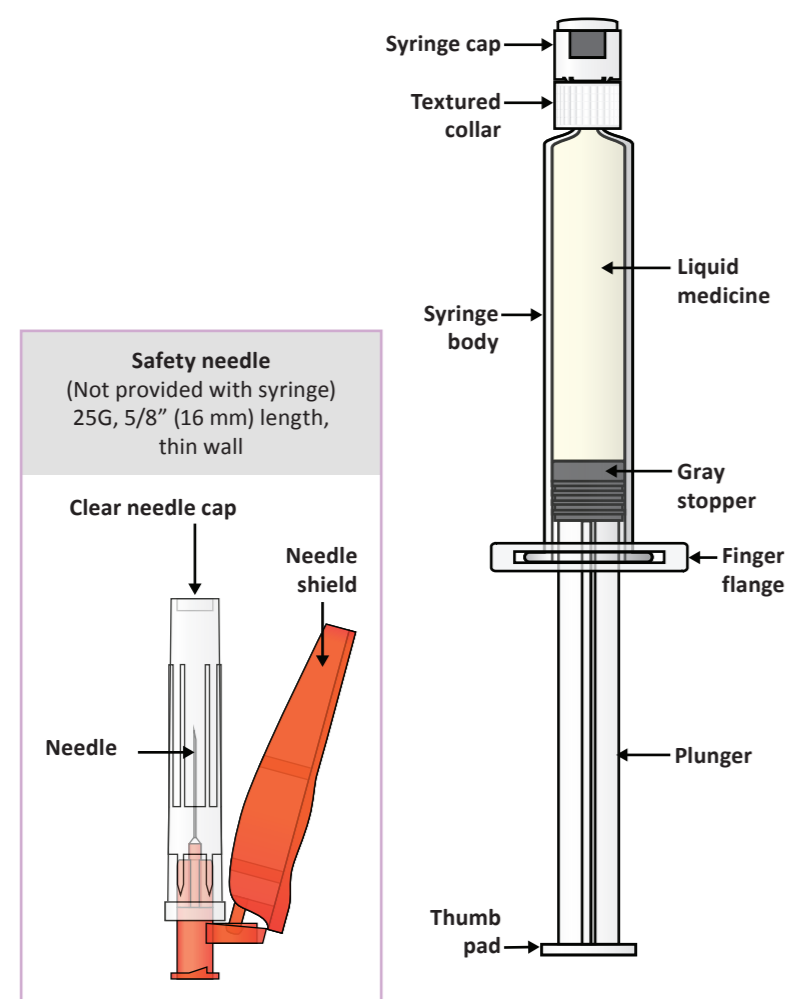
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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 pre-filled syringe is for single use only and cannot be reused.
 - **Do not** use the pre-filled syringe if it has been at room temperature for longer than 1 month.
 - **Do not** use the pre-filled syringe if the expiry date has passed.
 - **Do not** use the pre-filled syringe if it is cracked, broken, damaged or if the cap is missing. Report and return these damaged pre-filled syringes to the pharmacy.
 - **Do not** use the pre-filled syringe if the medicine is discoloured or contains particles. The medicine should appear clear to light yellow. A little cloudiness is normal.
 - **Do not** shake the pre-filled syringe.
- Storing Vyvgart pre-filled syringe**
- Store in a refrigerator (2 °C - 8 °C).
 - **Do not** freeze.
 - You can also store the unopened pre-filled syringe at room temperature in the original carton up to 30 °C for a single period of up to 1 month after removing it from the refrigerator. Discard it if it has not been used within the 1 month period or by the expiry date, whichever happens first.
 - Store in the original package in order to protect from light.
 - Keep this medicine out of the sight and reach of children.

Pre-filled syringe parts



Gathering and checking the supplies

1 Removing the carton from the refrigerator

- 1.1 Remove the pre-filled syringe carton from the refrigerator
- 1.2 Remove 1 pre-filled syringe from the carton and place any remaining pre-filled syringes back into the refrigerator for later use.
- 1.3 Remove the pre-filled syringe from the tray.

2 Checking the pre-filled syringe before use

- 2.1 Check the expiry date on the pre-filled syringe. **Do not** use the pre-filled syringe if the expiry date has passed.
- 2.2 Check the condition of the pre-filled syringe and the pre-filled syringe cap. **Do not** use the pre-filled syringe if it is cracked, broken, damaged, or if the cap is missing.
- 2.3 Check the appearance of the medicine in the pre-filled syringe. The medicine should look clear to light yellow in colour. A little cloudiness is normal. **Do not** use the pre-filled syringe if the medicine is discoloured or contains particles.

Preparing for the injection

3. Allowing the pre-filled syringe to warm to room temperature

Place the pre-filled syringe on a clean flat surface and let it sit for at least 30 minutes, to allow it to warm to room temperature.



Do not attempt to warm the pre-filled syringe in any other way. **Do not** use the pre-filled syringe if it has been at room temperature for longer than 1 month.

4. Gathering supplies and wash hands

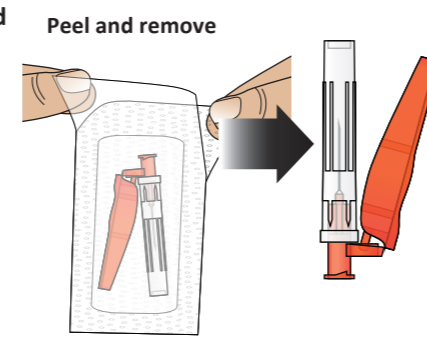
4.1 Gather the following supplies that are **not** provided with the pre-filled syringe

- Safety needle
- Alcohol swab
- Sharps container
- Sterile gauze and/or bandage (As needed)

4.2 Wash hands with soap and water.

5. Snap off the pre-filled syringe cap and attach the needle

5.1 Carefully open the needle package, remove the needle. Throw away the packaging via the household waste

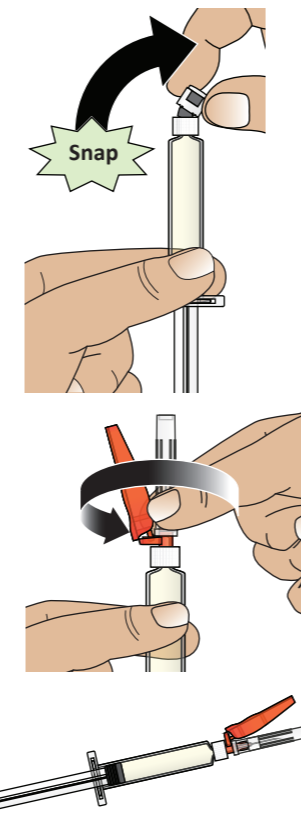


5.2 Bend the pre-filled syringe cap to one side to snap it off and remove it from the pre-filled syringe. Throw away the syringe cap in the household waste, and set the pre-filled syringe on a clean and flat surface.

Do not touch the tip of the pre-filled syringe after the cap has been removed.

5.3 Hold the pre-filled syringe in one hand and attach the needle to the pre-filled syringe by twisting it on (clockwise/to the right) until you feel resistance.

The needle is now attached to the pre-filled syringe.

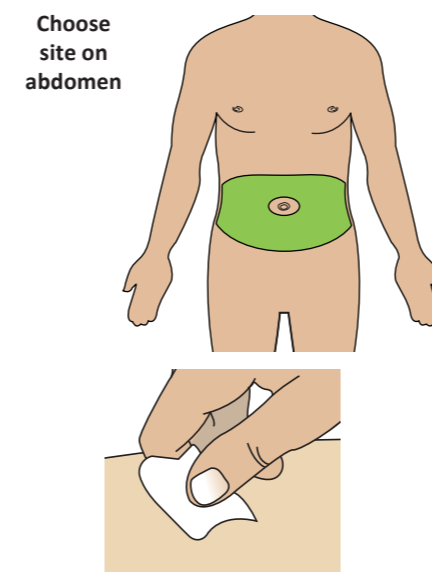


6. Choosing and cleaning the injection site on abdomen

6.1 Choose an injection site on the abdomen (belly area) at least 5 cm away from the belly button (navel). Change the injection site for each injection.

Do not inject into skin that is irritated, red, bruised, infected or scarred. **Do not** inject into a vein. The pre-filled syringe is for injection (under the skin) only.

6.2 Clean the chosen injection site with an alcohol swab and let it air dry. **Do not** blow on or touch the injection site after it has been cleaned.



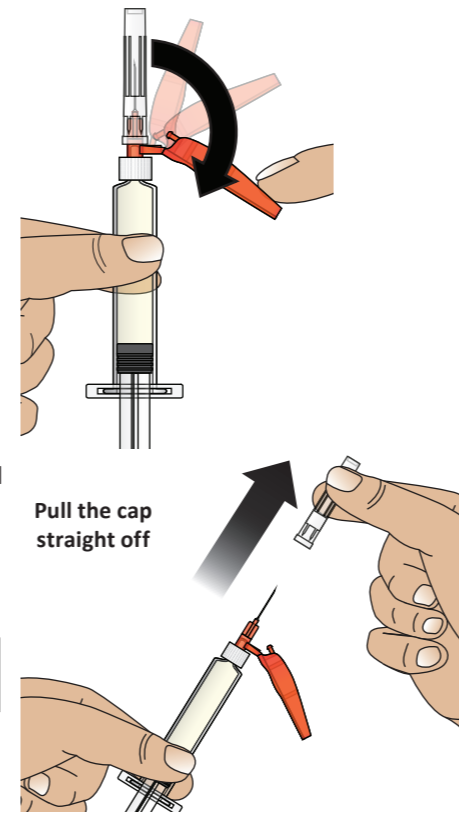
Injecting Vyvgart

7. Pulling back the needle shield and removing the needle cap

7.1 Pull the needle shield back. **Note:** The needle shield will be used after the injection to cover the needle and protect from needle-stick injuries

7.2 Hold the pre-filled syringe body and remove the clear needle cap by pulling it straight off of the needle. Throw away the needle cap into the household waste.

Do not put the needle cap back on the needle.



8. Giving the injection

8.1 Pinch the cleaned injection site. While pinching the skin, insert the needle at a 45 to 90 degree angle into the pinched skin. Then release the pinched skin.

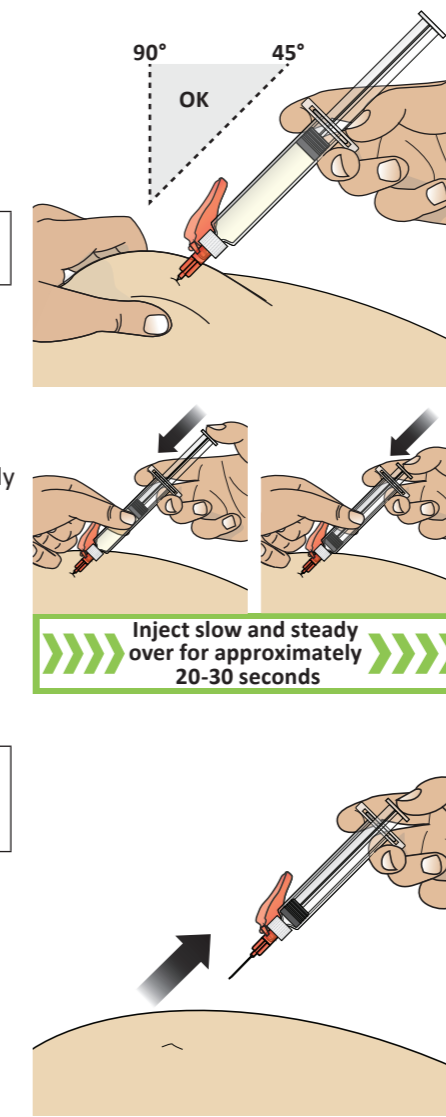
Do not pinch the skin too tightly as this can cause bruising.

8.2 Slowly press the plunger down all the way until it stops in order to inject the medicine. It will take approximately 20-30 seconds to inject all of the medicine. You will feel resistance as you press down. In case of discomfort inject more slowly.

It is ok if you need to pause or change your grip during the injection.

Do not try to force the plunger down quickly as this will make the plunger harder to press.

8.3 After all the liquid medicine is injected, remove the needle from the skin by pulling it straight out without changing the angle.



Disposing of the used syringe

9 Covering the needle and throwing away the used syringe

9.1 Carefully push the needle shield over the needle until it snaps into place and covers the needle. This helps to prevent needle-stick injuries.

Do not put the needle cap back on; only use the needle shield to cover the needle.

9.2 Throw away the used syringe, with the needle still attached, into the sharps container immediately after use.

Do not throw away (dispose of) loose needles and syringes in your household waste.

If you **do not** have a sharps 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;
- Is upright and stable;
- Is leak-resistant;
- Is appropriately labelled with a warning that hazardous waste is inside the container.

Dispose of the full container as instructed by your doctor, nurse or pharmacist.

10 Treating the injection site

If there is a small amount of blood or liquid at the injection site, press a gauze on it until the bleedings stops. If needed, you may apply a small adhesive bandage.

