Package leaflet: Information for the patient

Vyvgart 20 mg/ml concentrate for solution for infusion
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

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 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.

Infusion 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, or shortness of breath, feeling of losing consciousness, or skin rash during or after the infusion, then tell your doctor immediately.
You will be monitored for signs of an infusion reaction or allergic reaction during and for 1 hour after treatment.

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 medicine contains 67.2 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Vyvgart

The treatment will be given by your doctor or other health care provider. Your healthcare provider will first dilute the product. The dilution will be administered from a drip bag through a tube directly into one of your veins over the course of 1 hour.

What dose of Vyvgart you will receive and how often
The dose you receive will depend on your bodyweight, and will be administered in cycles of one infusion per week for 4 weeks. Your doctor will determine when further treatment cycles are needed.

Instructions for the healthcare provider on the proper use of this medicine are provided at the end of this document.

If you receive more Vyvgart than you should
If you suspect that you have been accidentally administered a higher dose of Vyvgart than prescribed, please contact your doctor for advice.

If you forget an appointment to receive Vyvgart
If you forget an appointment, please contact your doctor immediately for advice and see section below "If you stop using Vyvgart".

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.

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 infusion

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

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)
- headache during or after the administration of Vyvgart

Not known
- Allergic reactions during or after infusion
    - 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 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.

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

Do not use this medicine if visible particles are observed and/or the liquid in the vial is discoloured.

After dilution the product should be used immediately and the infusion (drip) should be completed within 4 hours of dilution. Allow the diluted medicinal product to reach room temperature before administration. The infusion should be completed within 4 hours of removal from the refrigerator.

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 20 mL vial contains 400 mg efgartigimod alfa (20 mg/mL).

The other ingredients are:
- sodium dihydrogen phosphate, monohydrate
- disodium hydrogen phosphate, anhydrous
- sodium chloride
- arginine hydrochloride
- polysorbate 80
- water for injections

What Vyvgart looks like and contents of the pack
Vyvgart is presented as a sterile concentrate for intravenous (IV) infusion (20 mL in a vial – pack size of 1).
Vyvgart is a liquid. It is colourless to slightly yellow, clear to almost clear.

Marketing Authorisation Holder and Manufacturer
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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 Sept 2023.

The following information is intended for healthcare professionals only:

Instructions for use for healthcare professionals handling Vyvgart

1. How is Vyvgart supplied?

Each vial contains 400 mg efgartigimod alfa at a concentration of 20 mg/mL, to be diluted in sodium chloride 9 mg/mL (0.9%) solution for injection.

2. Before administration

Reconstitution and dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis.

Vyvgart should be prepared for administration by a qualified healthcare professional using aseptic technique.

Using the formula in the table below, calculate the following:

- The dose of Vyvgart required based on the patient's bodyweight at the recommended dose of 10 mg/kg. For patients weighing over 120 kg use a bodyweight of 120 kg to calculate the dose. The maximum total dose per infusion is 1 200 mg. Each vial contains 400 mg of efgartigimod alfa at a concentration of 20 mg/mL.
- The number of vials needed.
- The volume of sodium chloride 9 mg/mL (0.9%) solution for injection. The total volume of diluted medicinal product is 125 mL.

Table 1. Formula

Step 1 – Calculate the dose (mg)	10 mg/kg x weight (kg)
Step 2 – Calculate the volume of concentrate (mL)	dose (mg) ÷ 20 mg/mL
Step 3 – Calculate the number vials	volume of concentrate (mL) ÷ 20 mL
Step 4 – Calculate the volume of sodium chloride 9 mg/mL (0.9%) solution for injection (mL)	125 mL – concentrate volume (mL)

3. Preparation and Administration

- Do not administer Vyvgart as an intravenous push or bolus injection.
- Vyvgart should only be administered via intravenous infusion as described below.

Preparation

- Visually inspect that the vial content is clear to slightly opalescent, colourless to slightly yellow, and devoid of particulate matter. If visible particles are observed and/or the liquid in the vial is discoloured, the vial must be discarded. Do not shake the vials.
- Using aseptic technique throughout the preparation of the diluted solution:
  - Gently withdraw the required amount of Vyvgart from the appropriate number of vials with a sterile syringe and needle. Discard any partially used or empty vials.
  - Transfer the calculated dose of the product into an infusion bag.
  - Dilute the withdrawn product by adding the calculated amount of sodium chloride 9 mg/mL (0.9%) solution for injection to make a total volume of 125 mL.

- Gently invert the infusion bag containing the diluted product **without shaking** to ensure thorough mixing of the product and the diluent.

- The efgartigimod alfa solution diluted in sodium chloride 9 mg/mL (0.9%) solution for injection can be administered using polyethylene (PE), polyvinyl chloride (PVC), ethylene vinyl acetate (EVA) and ethylene/polypropylene copolymer bags (polyolefins bags), as well as with PE, PVC and polyurethane/polypropylene infusion lines, together with polyurethane (PUR) or PVC filters with polyethersulfone (PES) or polyvinylidene fluoride (PVDF) filter membrane .

Administration

- Vyvgart should be administered via intravenous infusion by a healthcare professional. Do not administer as a push or bolus injection.
- Inspect the solution visually for particulate matter prior to administration.
- Infuse the total 125 mL of diluted medicine over 1 hour using a 0.2 µm filter. Administer the full amount of solution. After administration of the product, the line should be flushed with sodium chloride 9 mg/mL (0.9%) solution for injection.
- Administer immediately after dilution and complete the infusion of diluted solution within 4 hours of dilution.
- Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C to 8°C. From a microbiological point of view, unless the method of dilution precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Do not freeze. Allow the diluted medicine to reach room temperature before administration. Complete the infusion within 4 hours of removal from the refrigerator. The diluted medicine should not be heated in any other manner than via ambient air.
- Should infusion reactions occur, the infusion should be administered at a slower rate, interrupted or discontinued.
- Other medicines should not be injected into infusion side ports or mixed with Vyvgart.

4. Special Handling and Storage

Store the vials in a refrigerator (2 °C - 8 °C) until the time of use. Do not freeze. Store in the original package in order to protect from light.
Do not use this medicine after the expiry date which is stated on the carton after ‘EXP’. The expiry date refers to the last day of that month.