

What is VYVGART® (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection? VYVGART and VYVGART HYTRULO are both prescription medicines, each used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

SELECT IMPORTANT SAFETY INFORMATION

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections.

Generalized myasthenia gravis (gMG) is a rare, autoimmune, neuromuscular condition that causes muscle weakness and fatigue

MUSCLE WEAKNESS FROM gMG CAN CAUSE:

- » Eyelid drooping
- » Blurred or double vision
- » Difficulty speaking
- » Difficulty chewing/swallowing
- » Choking

- » Difficulty supporting neck
- » Shortness of breath/difficulty breathing
- » Weakness in the arms and legs
- » Difficulty walking/standing
- » Fatigue from repeated muscle use

gMG symptoms can make daily life more challenging and may limit one's ability to do everyday activities

UNDERSTANDING HARMFUL ACHR ANTIBODIES IS AN IMPORTANT PART OF UNDERSTANDING gMG



Antibodies, also known as immunoglobulins (Ig), are proteins produced by the immune system to help protect the body from infection and disease.



The immune system makes 5 different types of antibodies (IgG, IgA, IgE, IgD, IgM). IgG is the most common.



Sometimes the immune system mistakenly makes harmful IgG antibodies that target AChR. Patients with these harmful AChR antibodies have anti-AChR antibody positive gMG.

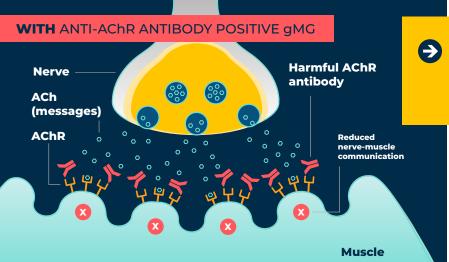
HARMFUL ACHR ANTIBODIES CAUSE gMG SYMPTOMS



While IgG antibodies continue to protect the body, harmful AChR antibodies disrupt communication between muscles and nerves.



This prevents muscles from getting some messages sent by nerves; this is what causes gMG symptoms.



→ Learn more about harmful AChR antibodies and gMG at ABOUTgMG.com

> ACh=acetylcholine; AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G Visit YYVGART.com/glossary for a glossary of terms.

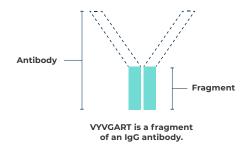






A FIRST-OF-ITS-KIND TREATMENT

VYVGART is the first FDA-approved treatment that uses a fragment of an IgG antibody to treat adults with anti-AChR antibody positive gMG



Choose the VYVGART option that is best for you



For **IV infusion**—given by inserting a needle into a vein so the medicine enters the bloodstream.

Pages 10 and 11: effectiveness and safety information



(efgartigimod alfa and hyaluronidase-qvfc) Subcutaneous Injection 180 mg/mL and 2000 U/mL vial For **subcutaneous injection**—given by delivering medicine into the layer beneath the skin.

Pages 14 and 15: effectiveness and safety information

IV=intravenous

Visit VYVGART.com/glossary for a glossary of terms.

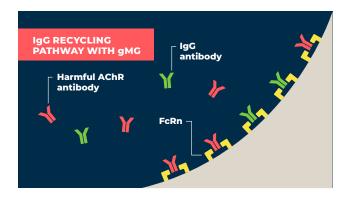
SELECT IMPORTANT SAFETY INFORMATION

More patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and observed lower white blood cell counts were mild to moderate in severity. Your healthcare provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART or VYVGART HYTRULO.



Harmful AChR antibodies cause gMG symptoms

Receptors called "FcRn" extend the life of IgG antibodies, including the harmful AChR antibodies that cause gMG symptoms. This allows harmful AChR antibodies to continue causing symptoms. IgG antibodies, including harmful AChR antibodies, that can't attach to FcRn are removed by the body.



SELECT IMPORTANT SAFETY INFORMATION

Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

VYVGART for IV infusion: Please see Important Safety Information throughout. Please see full Prescribing Information for <u>VYVGART for IV infusion</u>.



VYVGART causes IgG antibodies to be reduced, including the harmful AChR antibodies that cause gMG symptoms

VYVGART specifically works to reduce IgG antibodies, including gMG-causing, harmful AChR antibodies. VYVGART targets FcRn receptors, preventing many IgG antibodies, including the harmful AChR antibodies, from attaching. Harmful AChR antibodies that don't attach to FcRns are removed from the body and can no longer cause gMG symptoms.

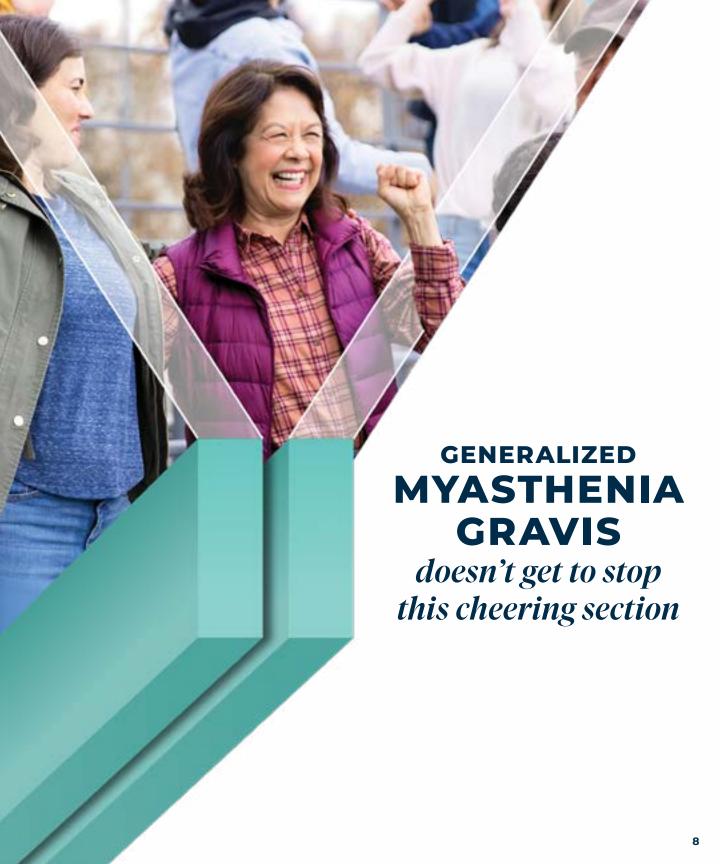


AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G Visit VYVGART.com/glossary for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

VYVGART for IV infusion: Please see Important Safety Information throughout. Please see full Prescribing Information for <u>VYVGART for IV infusion</u>.



VYVGART FOR **IV INFUSION**





VYVGART is a 1-hour IV infusion given at an infusion center, neurologist's office, or at home*

Visit VYVGART.com/glossary for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with VYVGART or VYVGART HYTRULO such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

^{*}In some cases, VYVGART may also be a given at home by a trained nurse. IV=intravenous



When added to their current gMG treatment, VYVGART helped patients in the study with anti-AChR antibody positive gMG achieve:

Improved daily abilities

68% (44 of 65) of patients on VYVGART achieved significant improvement in their ability to perform daily activities*

Compared to 30% (19 of 64) of patients on placebo plus current treatment

Reduced muscle weakness

63% (41 of 65) of patients on VYVGART achieved a significant reduction in muscle weakness[†]

Compared to 14% (9 of 64) of patients on placebo plus current treatment

VYVGART was evaluated in a global study of adults with anti-AChR antibody positive gMG.

The study examined the safety and effectiveness of VYVGART in 167 adults (18 years or older*) with gMG.

In addition to their current treatment, patients received either VYVGART or placebo.

*Improvement maintained for 4 or more weeks was measured by a decrease of 2 or more points on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, with the first reduction occurring no later than 1 week after the last infusion of treatment cycle 1. The MG-ADL scale assesses the impact of gMG on daily functions by measuring 8 signs or symptoms that are commonly affected in gMG. Each item is measured on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents the loss of ability to perform that function. Total scores range from 0 to 24 points, with a higher score showing more severe gMG.

†Improvement maintained for 4 or more weeks was measured by a decrease of 3 or more points on the Quantitative Myasthenia Gravis (QMG) scale, with the first reduction occurring no later than 1 week after the last infusion of treatment cycle 1. The QMG scale assesses muscle weakness in gMG based on 13 items. Each item is assessed on a 4-point scale, where a score of 0 represents no muscle weakness and a score of 3 represents severe muscle weakness. Total scores range from 0 to 39, with a higher score meaning muscle weakness is more severe.

‡Patients in Japan were 20 years or older.

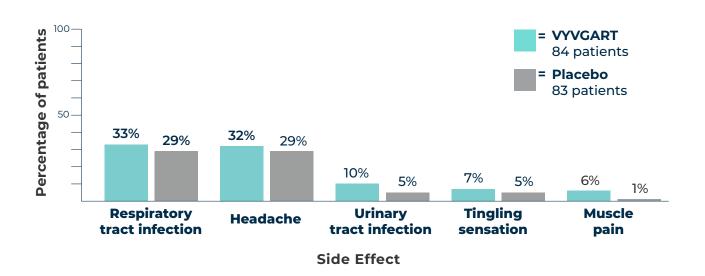
SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of efgartigimod-alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.



VYVGART was safe in treating most patients in the study and has a proven safety profile

In the study, the following side effects were reported in at least 5% of patients on VYVGART and more frequently than in patients on placebo



Most infections in patients on VYVGART were mild to moderate. Additionally, more patients on VYVGART vs. placebo had lower white blood cell counts that were mild to moderate in severity.

Hypersensitivity reactions including rash, swelling under the skin, and shortness of breath were observed in some VYVGART-treated patients.

AChR-acetylcholine receptor; gMG-generalized myasthenia gravis Visit VYVGART.com/glossary for a glossary of terms.





VYVGART HYTRULO FOR SUBCUTANEOUS INJECTION



VYVGART Hytrulo usually takes 30 to 90 seconds to inject and is given at an infusion center, doctor's office, or at home*†

VYVGART Hytrulo contains 2 active ingredients: efgartigimod alfa, which is the same active ingredient in VYVGART for IV infusion, and hyaluronidase (human recombinant). Hyaluronidase helps to increase the distribution and absorption of ingredients into the body. For more information on what efgartigimod alfa does, see pages 6 and 7.

IV=intravenous

*For at least 30 minutes after your injection, a healthcare professional will monitor you for reactions. †In some cases, VYVGART Hytrulo may also be given at home by a trained nurse.

SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with VYVGART or VYVGART HYTRULO such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

EFFECTIVENESS

VYVGART Hytrulo was found to be effective for adults with anti-AChR antibody positive gMG

The effectiveness of VYVGART Hytrulo was established through 2 studies.

In the VYVGART Hytrulo study, VYVGART Hytrulo for subcutaneous injection had a similar reduction in the harmful AChR antibodies that cause gMG symptoms as VYVGART for IV infusion.

In the VYVGART for IV infusion study, a reduction in harmful AChR antibodies was associated with improved daily abilities (reduction in total MG-ADL score).

See page 10 for study results.

VYVGART Hytrulo study design: The study compared antibody reduction in 110 adults (18 years or older) with gMG who remained on their current gMG treatment and were given either VYVGART Hytrulo for subcutaneous injection or VYVGART for IV infusion.



SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of efgartigimod-alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.





VYVGART Hytrulo was safe in treating most patients studied

The safety of VYVGART Hytrulo was established through 2 studies.

The overall safety of VYVGART Hytrulo for subcutaneous injection was consistent with the safety profile of VYVGART for IV infusion, except patients on VYVGART Hytrulo for subcutaneous injection experienced more injection site reactions.

In the VYVGART for IV infusion study, the most common side effects for VYVGART for IV infusion-treated patients were respiratory tract infection, headache, and urinary tract infection. Additionally, more patients on VYVGART for IV infusion vs. placebo had lower white blood cell counts that were mild to moderate in severity.

See page 11 for study results.

In the VYVGART Hytrulo study, the most common side effects of VYVGART Hytrulo-treated patients were injection site reactions, 38% (21 of 55), and headache. Injection site reactions included injection site rash, redness of the skin, itching sensation, bruising, pain, and hives.

In the VYVGART Hytrulo study and its long-term safety study:

- All injection site reactions were mild to moderate and didn't lead to treatment discontinuation
- The majority of injection site reactions occurred within 24 hours of injection and resolved on their own
- The majority of injection site reactions occurred during the first treatment cycle and decreased with each subsequent cycle

Hypersensitivity reactions including rash, swelling under the skin, shortness of breath, and hives were observed in some VYVGART Hytrulo-treated patients.

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous Visit VYVGART.com/glossary for a glossary of terms.



DOSING SCHEDULE

VYVGART is given in treatment cycles with an individualized break between cycles*

A treatment cycle consists of 1 treatment each week for 4 weeks (4 treatments per cycle)



Breaks between cycles are individualized because your next cycle of treatment is based on an evaluation of your gMG symptoms and side effects by your neurologist.* Track your symptoms to help your neurologist determine your next treatment cycle. The safety of starting the next treatment cycle sooner than 4 weeks from the last treatment of the previous treatment cycle has not been established.

SELECT IMPORTANT SAFETY INFORMATION

More patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and observed lower white blood cell counts were mild to moderate in severity. Your healthcare provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART or VYVGART HYTRULO.

^{*}If additional cycles are needed.



Track your symptoms to help your neurologist determine your next treatment cycle



Download the MG-ADL assessment tool on VYVGART.com to start tracking your symptoms. If you are enrolled in My VYVGART Path, a physical journal will be mailed to you and a Nurse Case Manager can show you how to use it as you get started.



Your neurologist will work with you to help determine if and when you need another treatment cycle, with the aim to help manage your symptoms.*

Three ways to find your treatment location

- Reach out to your doctor's office
- 2 Search the Infusion Center Locator at VYVGART.com
- 3 Call 1-833-MY-PATH-1 (1-833-697-2841) to speak to someone

*If additional cycles are needed. gMG=generalized myasthenia gravis Visit VYVGART.com/glossary for a glossary of terms.

→ Find out more about VYVGART treatment schedules and learn how to track your symptoms on VYVGART.com

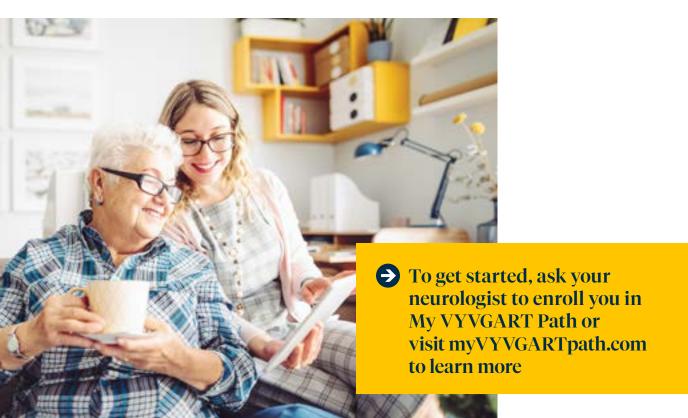
SELECT IMPORTANT SAFETY INFORMATION

Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with VYVGART or VYVGART HYTRULO such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

My V V V GART Path

Here for you during your VYVGART treatment journey

My VYVGART Path is a **Patient Support Program** that provides personalized support from a Nurse Case Manager and committed support team. They are dedicated to listening to you and answering questions you may have about VYVGART during your treatment journey.





Understand your VYVGART treatment

A Nurse Case Manager can provide educational information to help you learn about VYVGART for IV infusion and VYVGART Hytrulo for subcutaneous injection and understand the infusion and injection processes.



Feel empowered with resources and information

Nurse Case Managers can support you throughout your VYVGART treatment journey to help you in following your doctor's treatment plan.



Navigate the insurance process

You may have questions about your insurance coverage, want to know more about the cost of treatment, or just need information about your out-of-pocket costs for VYVGART. With My VYVGART Path, you'll find support in understanding each step of the insurance process.



Understand potential financial assistance programs

If you have financial concerns or gaps in insurance coverage for your VYVGART therapy, a Nurse Case Manager is here for you with information and support.



FREQUENTLY ASKED QUESTIONS

How is VYVGART given?

VYVGART is available as VYVGART for IV infusion or as VYVGART Hytrulo for subcutaneous injection. An IV infusion is given by inserting a needle into a vein so that medicine immediately enters the bloodstream. A subcutaneous injection delivers medicine into the layer beneath the skin.

Is VYVGART intended to be taken with other medications?

Yes, in the studies, patients stayed on their current gMG treatment while receiving VYVGART for IV infusion or VYVGART Hytrulo for subcutaneous injection. Talk to your doctor about the medications you are taking as part of your treatment plan.

What are the most common side effects of VYVGART?

Out of 84 patients in the study treated with VYVGART for IV infusion, the most common side effects included respiratory tract infection (33%), headache (32%), urinary tract infection (10%), tingling sensation (7%), and muscle pain (6%).* Most infections in patients on VYVGART for IV infusion

were mild to moderate. Additionally, more patients on VYVGART for IV infusion vs. placebo had lower white blood cell counts that were mild to moderate in severity.

The overall safety of VYVGART Hytrulo for subcutaneous injection was consistent with the safety profile of VYVGART for IV infusion, except patients on VYVGART Hytrulo for subcutaneous injection experienced more injection site reactions.

In the VYVGART Hytrulo study, the most common side effects of VYVGART Hytrulo-treated patients were injection site reactions, 38% (21 of 55), and headache. Injection site reactions included injection site rash, redness of the skin, itching sensation, bruising, pain, and hives.

In the VYVGART Hytrulo study and its longterm safety study, all injection site reactions were mild to moderate and didn't lead to treatment discontinuation. The majority occurred within 24 hours of injection and resolved on their own. The majority occurred during the first treatment cycle and decreased with each subsequent cycle.

*In ≥5% treated with VYVGART and more frequently than placebo.

SELECT IMPORTANT SAFETY INFORMATION

VYVGART and VYVGART HYTRULO can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to treatment discontinuation. Your healthcare provider should monitor you during and after treatment and discontinue VYVGART or VYVGART HYTRULO if needed. Tell your healthcare provider immediately about any undesirable reactions to VYVGART or VYVGART HYTRULO.

Do I have to get any vaccines before taking VYVGART?

Some types of vaccines are not recommended while taking VYVGART. Talk to your doctor about vaccines, including when you need to receive age-appropriate vaccines, before starting a treatment cycle of VYVGART.

How many patients in the VYVGART for IV infusion study continued to the extended safety study?

91% of the patients in the study who were eligible chose to enter a 3-year extension safety study where they would receive VYVGART for IV infusion.

What should I do if I miss a treatment?

If you miss an IV infusion or subcutaneous injection, VYVGART may be given up to 3 days after the scheduled treatment day. Work with your neurologist to reschedule your next treatment.

How do I track my symptoms?

Download the MG-ADL assessment tool on VYVGART.com to start tracking your symptoms. If you are enrolled in My VYVGART Path, a physical journal will be mailed to you and a Nurse Case Manager can show you how to use it as you get started.

How do I join the My VYVGART Path program?

After you and your neurologist decide on VYVGART, your doctor's office will be able to enroll you in My VYVGART Path. Then, a Nurse Case Manager will call, welcome you to the program, and offer assistance as you get started on your treatment journey with VYVGART for IV infusion or VYVGART Hytrulo for subcutaneous injection.

IV=intravenous

Visit VYVGART.com/glossary for a glossary of terms.



→ More information available at VYVGART.com

SELECT IMPORTANT SAFETY INFORMATION

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections. These are not all the possible side effects of VYVGART or VYVGART HYTRULO. Call your doctor for medical advice about side effects.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about VYVGART® (efgartigimod alfa-fcab) for intravenous (IV) infusion and VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection?

VYVGART and VYVGART HYTRULO may cause serious side effects, including:

- Infection. VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcabtreated patients were urinary tract and respiratory tract infections. More patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and observed lower white blood cell counts were mild to moderate in severity. Your healthcare provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART or VYVGART HYTRULO. Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with VYVGART or VYVGART HYTRULO such as fever, chills, frequent and/ or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain. If a serious infection occurs, your doctor will treat your infection and may even stop your VYVGART or VYVGART HYTRULO treatment until the infection has resolved.
- Undesirable immune reactions (hypersensitivity reactions). VYVGART and VYVGART HYTRULO can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to treatment discontinuation. Your healthcare provider should monitor you during and after treatment and discontinue VYVGART or VYVGART HYTRULO if needed. Tell your healthcare provider immediately about any undesirable reactions to VYVGART or VYVGART HYTRULO.

Before taking VYVGART or VYVGART HYTRULO, tell your healthcare provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection.
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your healthcare provider whether you need to receive ageappropriate immunizations before initiation of a new treatment cycle with VYVGART or VYVGART HYTRULO. The use of vaccines during treatment with VYVGART or VYVGART HYTRULO has not been studied, and the safety with live or liveattenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the common side effects of VYVGART and VYVGART HYTRULO?

The most common side effects of efgartigimodalfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.

These are not all the possible side effects of VYVGART and VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

What is VYVGART for IV infusion and what is VYVGART HYTRULO for subcutaneous injection?

VYVGART and VYVGART HYTRULO are both prescription medicines, each used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

Please see the full Prescribing Information for <u>VYVGART</u> and the full Prescribing Information for <u>VYVGART HYTRULO</u>, and talk to your doctor.





VÝVGART®Hytrulo

(efgartigimod alfa and hyaluronidase-qvfc) Subcutaneous Injection 180 mg/mL and 2000 U/mL vial

Picture your life in motion



When added to their current gMG treatment, VYVGART for IV infusion helped most patients in the study with anti-AChR antibody positive gMG achieve improved daily abilities*



VYVGART Hytrulo was found to be effective for adults with anti-AChR antibody positive aMG



VYVGART for IV infusion and VYVGART Hytrulo for subcutaneous injection were safe in treating most patients studied

Talk to your neurologist to see if VYVGART is right for you



Use the camera on your smartphone to scan the OR code and download your VYVGART Doctor Discussion Guide.

*Improvement maintained for 4 or more weeks was measured by a decrease of 2 or more points on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, with the first reduction occurring no later than I week after the last infusion of treatment cycle 1. The MG-ADL scale assesses the impact of gMG on daily functions by measuring 8 signs or symptoms that are commonly affected in gMG. Each item is measured on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents the loss of ability to perform that function. Total scores range from 0 to 24 points, with a higher score showing more severe gMG.

AChR-acetylcholine receptor; gMG-generalized myasthenia gravis; IV-intravenous Visit VYVGART.com/glossary for a glossary of terms.



Call 1-833-VYVGART (1-833-898-4278) or visit VYVGART.com to find out more

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