VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL | 200 mg/mL and 2000 U/mL

VYVGART®
(efgartigimod alfa-fcab)
Intravenous Injection
400 mg/20 mL vial

Could a **unique approach** to treating anti-AChR antibody positive gMG help your adult patients?[1-3]

Find out how **VYVGART Hytrulo** for SC injection and **VYVGART** for IV infusion utilize the **first and only** IgG Fc-antibody fragment to target FcRn[1-3]

AChR=acetylcholine receptor; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; IV=intravenous; SC=subcutaneous.

INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYVGART and VYVGART HYTRULO are contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART or VYVGART HYTRULO, respectively. VYVGART HYTRULO is also contraindicated in patients with serious hypersensitivity to hyaluronidase. Reactions have included anaphylaxis and hypotension leading to syncope.

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

The **first and only** IgG Fc-antibody fragment for the treatment of gMG in adult patients who are anti-AChR antibody positive[1,3]

VYVGART, also known as efgartigimod alfa, is engineered for affinity to FcRn[1,4]

Efgartigimod alfa is an Fc-antibody fragment* that targets and blocks FcRn to decrease IgG antibodies, including AChR autoantibodies, resulting in a decrease of pathogenic activity at the NMJ[1,3,4]

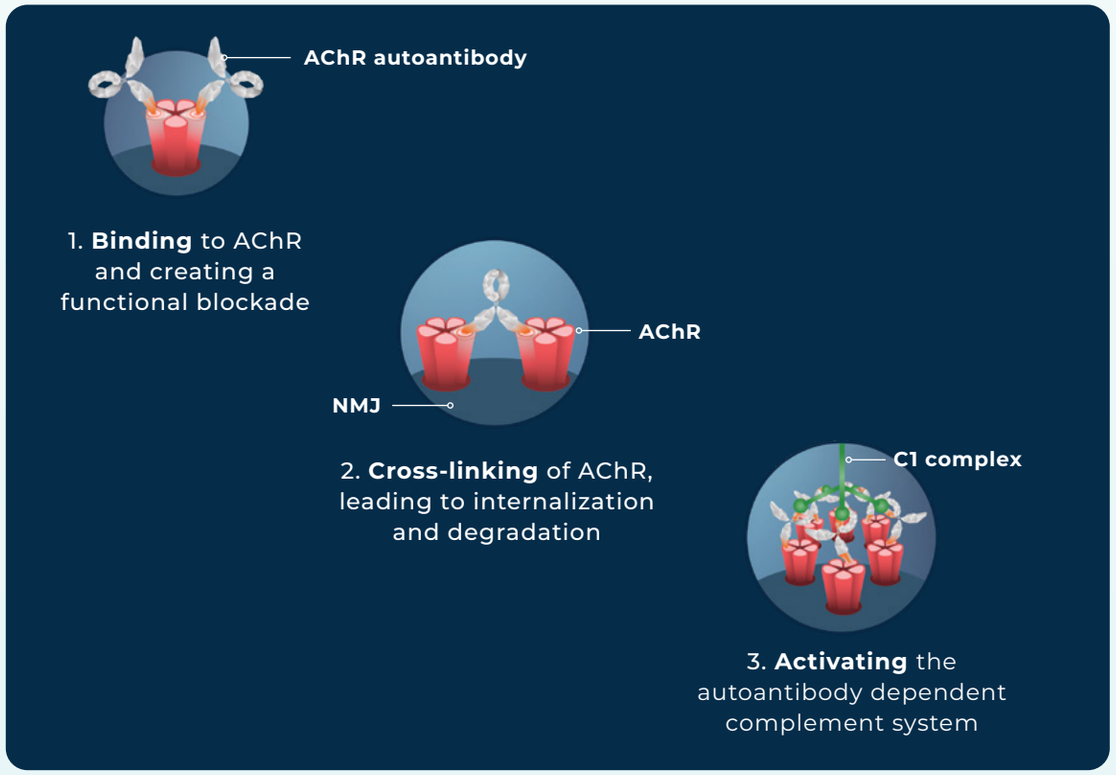
VYVGART Hytrulo is a coformulation of efgartigimod alfa (the same active ingredient in VYVGART for IV infusion) and hyaluronidase. By depolymerizing hyaluronan, hyaluronidase increases permeability of the subcutaneous tissue.[2]

*Human IgG-derived.
AChR=acetylcholine receptor; Fab=fragment, antigen-binding; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; IV=intravenous; NMJ=neuromuscular junction.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS
Infections
VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients).

AChR autoantibodies exert a direct pathogenic effect in gMG[5-9]

AChR autoantibodies disrupt neurotransmission in 3 ways[5-9]



C1=complement component 1.

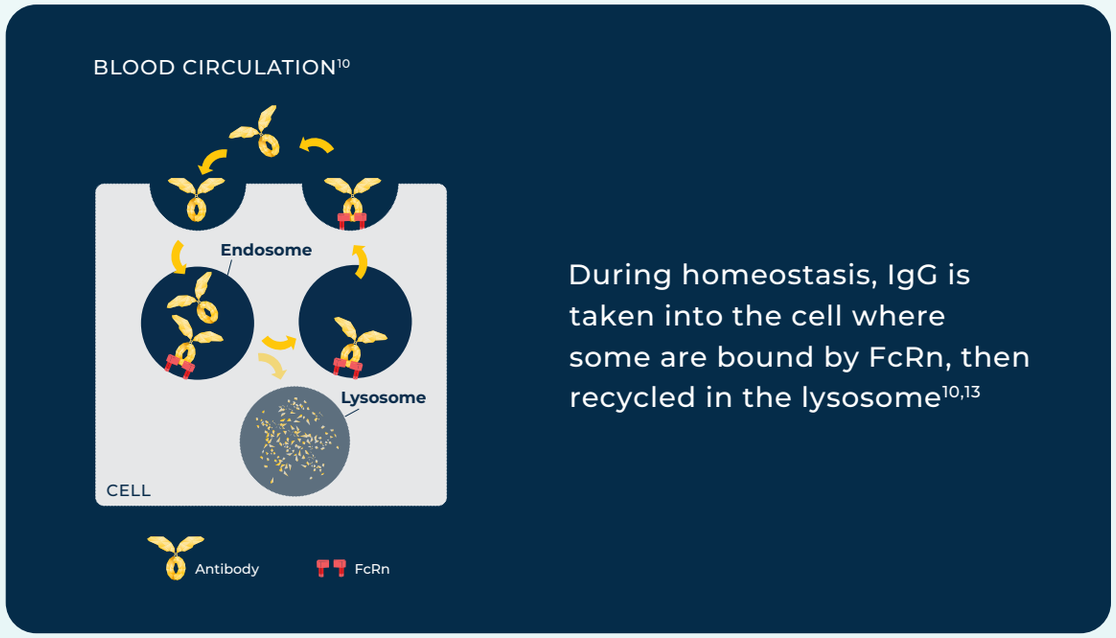
IMPORTANT SAFETY INFORMATION (cont'd)
Infections (cont'd)
Patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively).

Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) | VYVGART® (efgartigimod alfa-fcab)

FcRn plays a key role in gMG by perpetuating IgG antibodies[5-10]

- **FcRn binds IgG antibodies**, preventing them from being destroyed in the lysosome
- **FcRn helps maintain high levels** of circulating IgG antibodies, including AChR autoantibodies
- **FcRn perpetuates the ability** of AChR autoantibodies to attack structures such as AChR and damage the NMJ



AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; NMJ=neuromuscular junction.

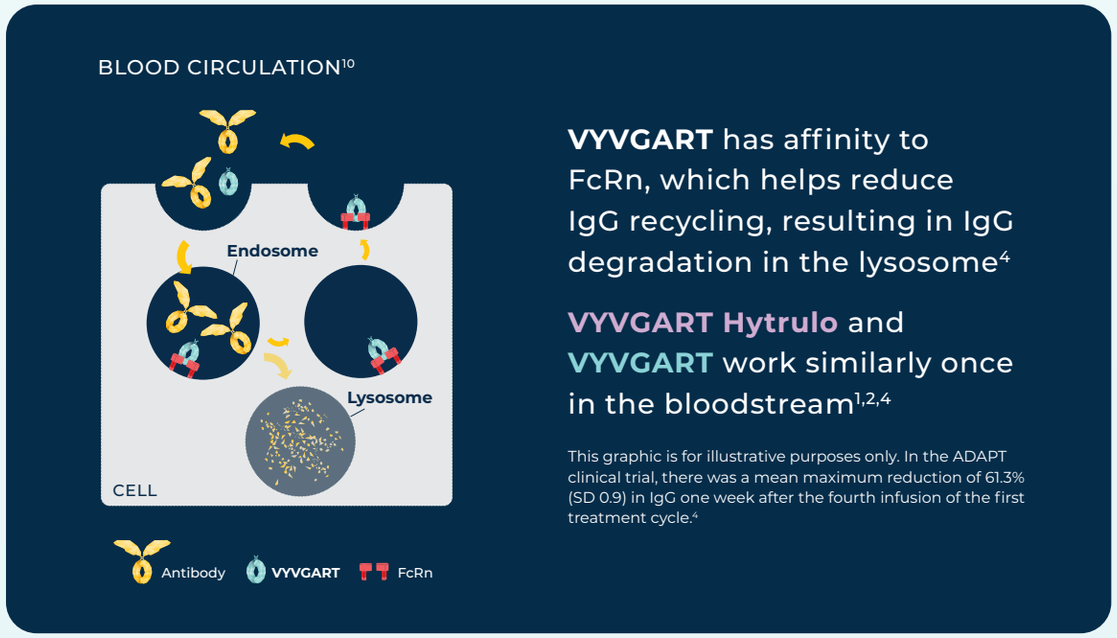
IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections.

VYVGART targets FcRn—a unique approach in the treatment of anti-AChR antibody positive gMG[1,3]

- **Block FcRn: VYVGART** competes with IgG antibodies, including AChR autoantibodies, in binding to and blocking FcRn[1,4]
- **Reducing IgG:** Unbound IgG antibodies, including AChR autoantibodies, are then destroyed in the lysosome, which results in their clearance[1,5,6,10]
- **Restoring function:** By binding to and blocking FcRn, **VYVGART** helps clear circulating IgG antibodies, including AChR autoantibodies, that cause NMJ damage and dysfunction[1,11,12]



IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

If serious infection occurs, administer appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

Infections

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients). Patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

Immunization

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART or VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART or VYVGART HYTRULO are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Monitor for clinical signs and symptoms of hypersensitivity reactions during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

Infusion-Related Reactions

Infusion-related reactions have been reported with VYVGART in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

Infusion/Injection-Related Reactions

Infusion-related reactions have been reported with intravenous efgartigimod alfa-fcab in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion/injection-related reaction occurs, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART HYTRULO following a severe infusion/injection-related reaction. If a mild to moderate infusion/injection-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion/injection rates, and pre-medications.

ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥10%) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously. Most injection site reactions occurred during the first treatment cycle, and the incidence decreased with each subsequent cycle.

USE IN SPECIFIC POPULATIONS

Pregnancy

As VYVGART and VYVGART HYTRULO are expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or efgartigimod alfa or hyaluronidase from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART HYTRULO.

You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

Dosage Forms and Strengths:

VYVGART Hytrulo is available as a single-dose subcutaneous injection containing: 200 mg/mL of efgartigimod alfa and 2,000 U/mL of hyaluronidase per prefilled syringe, or 180 mg/mL of efgartigimod alfa and 2,000 U/mL of hyaluronidase per vial.

VYVGART is available as a single-dose injection for intravenous use containing 400 mg/20 mL of efgartigimod alfa-fcab per vial.

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VYVGART for IV infusion and **VYVGART Hytrulo** for SC injection: the combined #1 **prescribed FDA-approved biologic treatments** for adults with anti-AChR antibody positive gMG*

Find out more about the clinical data behind VYVGART Hytrulo and VYVGART at VYVGARTHCP.com/gMG

***Based on IQVIA LAAD from January 2023 to December 2024. Data is based on validated open claims of VYVGART for IV infusion, VYVGART Hytrulo for SC injection, oral products and other biologics that have been approved by the FDA for the treatment of adults with generalized myasthenia gravis. Patients who had more than one medical claim in this data set were counted only once, based on a pre-defined hierarchy.**

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous; LAAD=Longitudinal Access and Adjudication Data; SC=subcutaneous.

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References: 1. VYVGART. Prescribing information. argenx US Inc; 2025. **2.** VYVGART Hytrulo. Prescribing information. argenx US Inc; 2025. **3.** Wolfe GI et al. *J Neurol Sci*. 2021;430:118074. doi:10.1016/j.jns.2021.118074 **4.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **5.** Roopenian DC, Akilesh S. *Nat Rev Immunol*. 2007;7(9):715-725. doi:10.1038/nri2155 **6.** Ward ES, Ober RJ. *Trends Pharmacol Sci*. 2018;39(10):892-904. doi:10.1016/j.tips.2018.07.007 **7.** Gilhus NE et al. *Nat Rev Neurol*. 2016;12(5):259-268. doi:10.1038/nrneurol.2016.44 **8.** Huijbers MG et al. *J Intern Med*. 2014;275(1):12-26. doi:10.1111/joim.12163 **9.** Mantegazza R et al. *Neuropsychiatr Dis Treat*. 2011;7:151-160. doi:10.2147/NDT.S8915 **10.** Ulrichts P et al. *J Clin Invest*. 2018;128(10):4372-4386. doi:10.1172/JCI97911 **11.** Koneczny I, Herbst R. *Cells*. 2019;8(7):671. doi:10.3390/cells8070671 **12.** Howard JF Jr et al. *Neurology*. 2019;92(23):e2661-e2673. doi:10.1212/WNL.0000000000007600 **13.** Sesarman A et al. *Cell Mol Life Sci*. 2010;67(15):2533-2550. doi:10.1007/s00018-010-0318-6

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