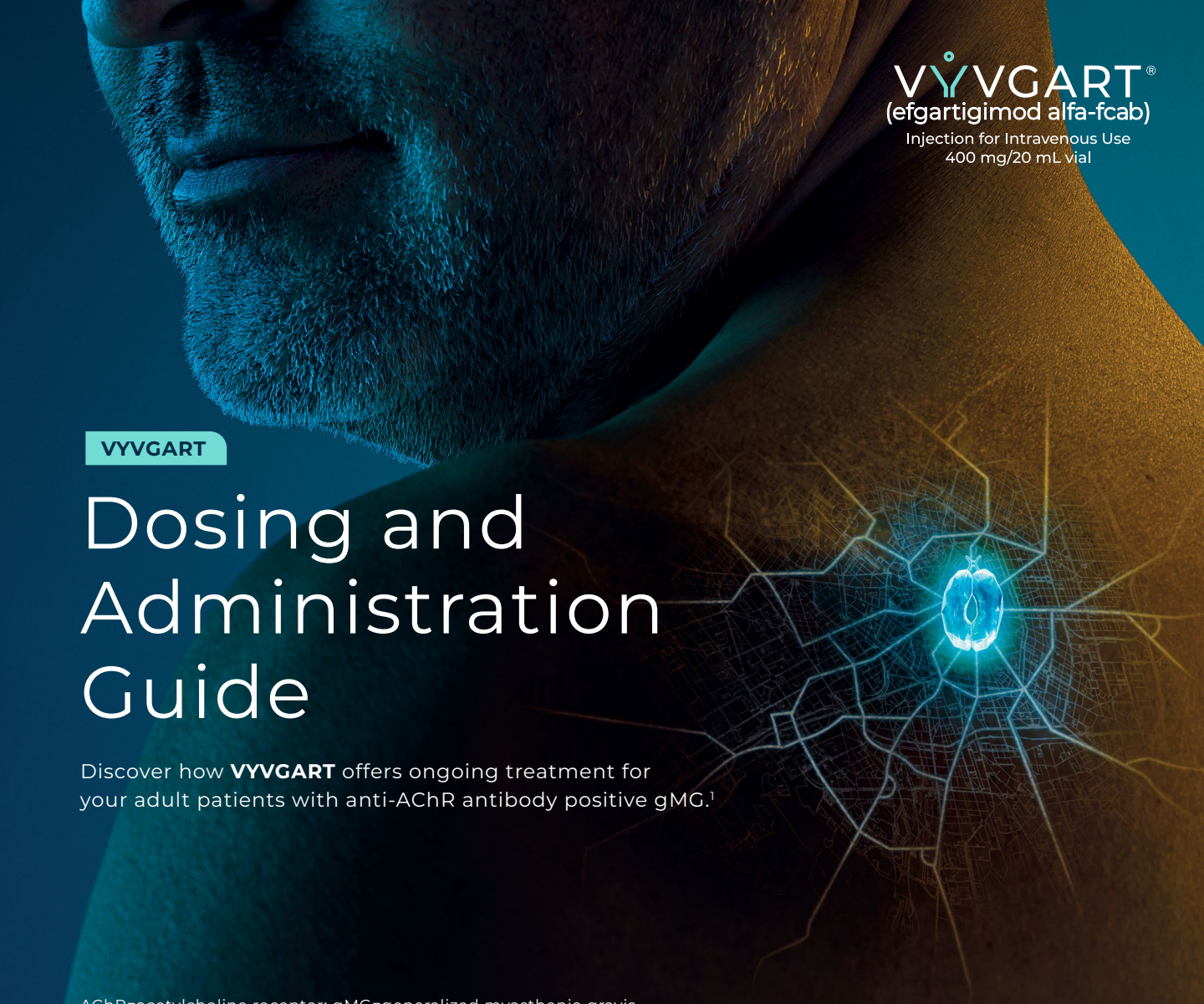
VYVGART®
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

VYVGART

Dosing and Administration Guide

Discover how **VYVGART** offers ongoing treatment for your adult patients with anti-AChR antibody positive gMG.[1]



AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.
Patient portrayal

INDICATION

VYVGART® (efgartigimod alfa-fcab) is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information throughout and full Prescribing Information.

VYVGART: ongoing treatment for effective symptom management[1]*

Recommended dose and dose schedule from Prescribing Information:

VYVGART: **1 TREATMENT CYCLE**[1]

1-HOUR IV INFUSION PER WEEK **FOR 4 WEEKS**
(10 mg efgartigimod alfa-fcab/kg) (weight-based)†

The recommended dose of **VYVGART** (efgartigimod alfa-fcab) is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks.‡

Administer **subsequent treatment cycles** based on clinical evaluation[1]

The safety of initiating subsequent cycles sooner than 4 weeks from the last infusion of the previous treatment cycle has not been established.[1,2]

*MG-ADL response was defined as a ≥2-point reduction in total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.[1]

†In patients weighing 265 lbs (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.[1]

‡In the ADAPT phase 3 clinical trial, all patients received an initial cycle, with subsequent cycles administered according to individual clinical evaluation when their MG-ADL score was at least 5 (with >50% MG-ADL nonocular) and if the patient was an MG-ADL responder, when they no longer had a clinically meaningful decrease (defined as having a ≥2-point improvement in total MG-ADL score) compared to baseline. The minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles were possible in the 26-week study.[1,2]

IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living.

IMPORTANT SAFETY INFORMATION (cont'd)

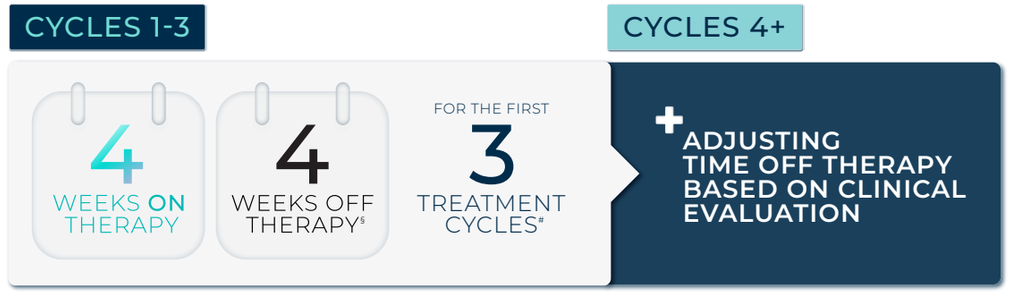
WARNINGS AND PRECAUTIONS

Infection

VYVGART may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% for VYVGART vs 5% for placebo) and respiratory tract infections (33% for VYVGART vs 29% for placebo). Patients on VYVGART 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).

An example approach:

Based on the most commonly observed schedule from a post-hoc analysis of ADAPT+ and ADAPT-SC+[3§‖]



For **cycles 1-3**, this example approach shows **4 weeks** on and **4 weeks** off therapy for 3 cycles.[3]

For subsequent cycles, continue evaluating the appropriate time off therapy based on clinical evaluation.[3]

Study Limitations: The distribution of average cycle duration in ADAPT+ and ADAPT-SC+ were post-hoc descriptive analyses not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

§ADAPT+ and ADAPT-SC+ were single-arm, open-label studies evaluating the long-term safety and tolerability of VYVGART and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc).[4,5]

‖Analysis included all complete cycles, defined as cycles not interrupted by the cut-off/final study date of December 1, 2022, or a single incomplete cycle of at least 28 days.[3]

¶Four weeks off starts after the last infusion of the most recent cycle.[3]

#A cycle consists of 4 once-weekly doses over 22 days.[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay VYVGART administration 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 VYVGART until the infection has resolved.

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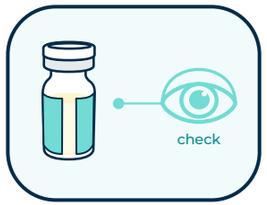
Preparation instructions for **VYVGART**[1]

Prior to administration, VYVGART single-dose vials require dilution in 0.9% Sodium Chloride Injection, USP, to make a total volume to be administered of 125 mL.

Check that the **VYVGART** solution is clear to slightly opalescent and colorless to slightly yellow. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if opaque particles, discoloration, or other foreign particles are present.



Use aseptic technique when preparing the **VYVGART** diluted solution for intravenous infusion. Each vial is for single-dose only. Discard any unused portion.

STEP 1 Calculate the dose (mg), total drug volume (mL) of **VYVGART** solution required, and the number of vials needed based on the recommended dose according to the patient's body weight. Each vial contains a total of 400 mg of **VYVGART** at a concentration of 20 mg per mL.

STEP 2 Gently withdraw the calculated dose of **VYVGART** from the vial(s) with a sterile syringe and needle. Discard any unused portion of the vials.

STEP 3 Dilute the withdrawn **VYVGART** with 0.9% Sodium Chloride Injection, USP to make a total volume of 125 mL for intravenous infusion.

STEP 4 Gently invert the infusion bag containing the diluted **VYVGART** without shaking to ensure thorough mixing of the product and the diluent.

STEP 5 The diluted solution can be administered using polyethylene (PE), polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), or ethylene/polypropylene copolymer bags (polyolefins bags), and with PE, PVC, EVA, or polyurethane/polypropylene infusion lines.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

Immunization with vaccines during VYVGART treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with VYVGART. 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 patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

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Dosing calculations for VYVGART[1]

Reference guide for calculating the appropriate dose of VYVGART:

Patient weight kg (lbs)	Dose mg	Drug volume mL	Vials needed per dose	Vials needed per cycle
55 (121)	**550**	**27.5**	**2**	**8**
60 (132)	**600**	**30**	**2**	**8**
65 (143)	**650**	**32.5**	**2**	**8**
70 (154)	**700**	**35**	**2**	**8**
75 (165)	**750**	**37.5**	**2**	**8**
80 (176)	**800**	**40**	**2**	**8**
85 (187)	**850**	**42.5**	**3**	**12**
90 (198)	**900**	**45**	**3**	**12**
95 (209)	**950**	**47.5**	**3**	**12**
100 (220)	**1000**	**50**	**3**	**12**
105 (231)	**1050**	**52.5**	**3**	**12**
110 (243)	**1100**	**55**	**3**	**12**
115 (254)	**1150**	**57.5**	**3**	**12**

In patients weighing 120 kg (265 lbs) or more, the recommended dose is 1,200 mg (3 vials) per infusion.

Find your patient's appropriate dose of VYVGART using our interactive dosing calculator at VYVGARTHCP.com/dosing

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Storing VYVGART after dilution:

VYVGART does not contain preservatives. Administer immediately after dilution and complete the infusion within 4 hours of dilution

If immediate use is not possible, the diluted solution may be stored refrigerated at 2 °C to 8 °C (36 °F to 46 °F) for up to 8 hours. Do not freeze. Protect from light. Allow the diluted drug to reach room temperature before administration. Complete the infusion within 4 hours of removal from the refrigerator. Do not heat the diluted drug in any manner other than via ambient air.

Please review Preparation and Administration Instructions in section 2.3 of the VYVGART Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

Infused-Related Reactions (cont'd)

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.

ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

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Administration instructions for VYVGART[1]

VYVGART should be administered via intravenous infusion by a healthcare professional.

STEP 1

Visually inspect **VYVGART** diluted solution for particles or discoloration prior to administration. Do not use if it is discolored or if opaque or foreign particles are seen.

STEP 2

Infuse the total 125 mL of diluted solution intravenously over one hour via a 0.2 micron in-line filter.

STEP 3

After administration of **VYVGART**, flush the entire line with 0.9% Sodium Chloride Injection, USP.

STEP 4

Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue administration of **VYVGART** and institute appropriate supportive measures.

Other medications should not be injected into infusion side ports or mixed with VYVGART

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

Pregnancy

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

Hypersensitivity and infusion-related reactions:

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in **VYVGART**-treated patients. Hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation.

Postmarketing experience with **VYVGART** included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation.

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab 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 and any potential adverse effects on the breastfed infant from VYVGART or from the underlying maternal condition.

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).

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INDICATION AND IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

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References: 1. VYVGART. Prescribing information. argenx US Inc; 2023. **2.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **3.** Data on file, argenx US Inc. December 2023. **4.** ClinicalTrials.gov. NCT03770403. Accessed December 12, 2023. https://clinicaltrials.gov/study/NCT03770403 **5.** ClinicalTrials.gov. NCT04818671. Accessed December 12, 2023. https://clinicaltrials.gov/study/NCT04818671

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Visit
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Not actual size.

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