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

A Guide to Dosing and Administration

Learn how this treatment can be tailored to your patient's individual needs based on clinical evaluation.[1,2]

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

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 infection (33% for VYVGART vs 29% for placebo).

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

VYVGART: an individualized dosing schedule based on clinical evaluation[1,3]

The recommended dose of VYVGART is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks.

1 TREATMENT CYCLE = 4 INFUSIONS (10 mg/kg each)

1-hour infusion per week for 4 weeks

SUBSEQUENT TREATMENT CYCLES

Administer subsequent treatment cycles based on clinical evaluation*

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

You may find it helpful for your patients to track their gMG symptoms and any adverse reactions during treatment to assist you with determining their next treatment cycle.

*In the ADAPT phase 3 clinical trial, all patients received an initial cycle, with subsequent cycles administered based on 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. gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living.

IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

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). 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 is 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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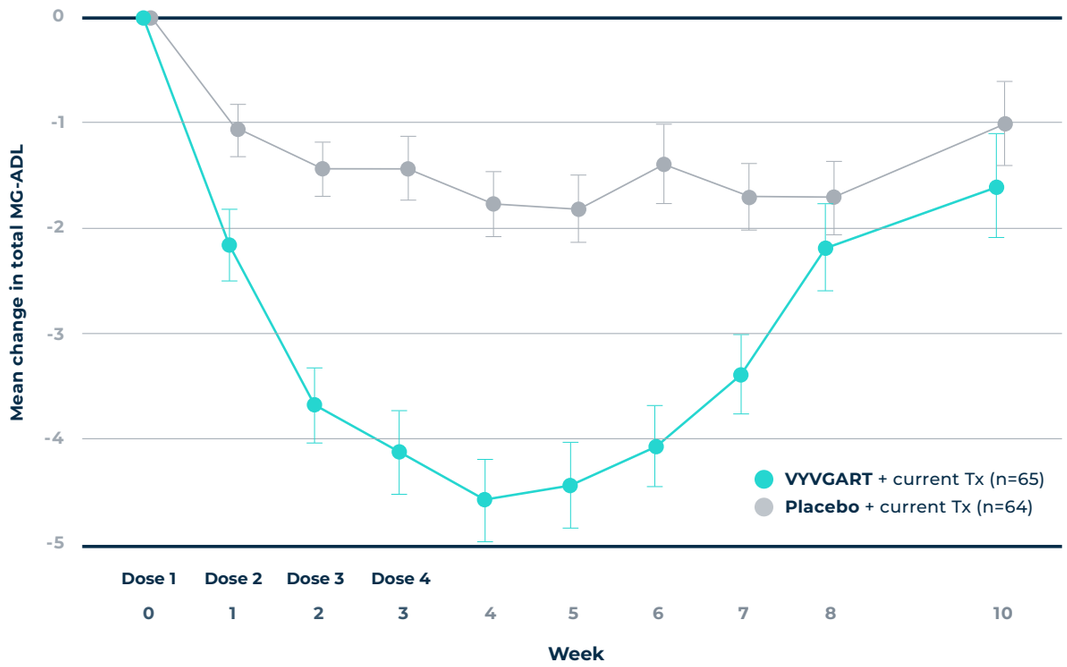
Mean change in MG-ADL from baseline over time in the ADAPT clinical trial (first treatment cycle)[1,3]*



*Clinical trial data from anti-AChR antibody positive VYVGART-treated population.
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

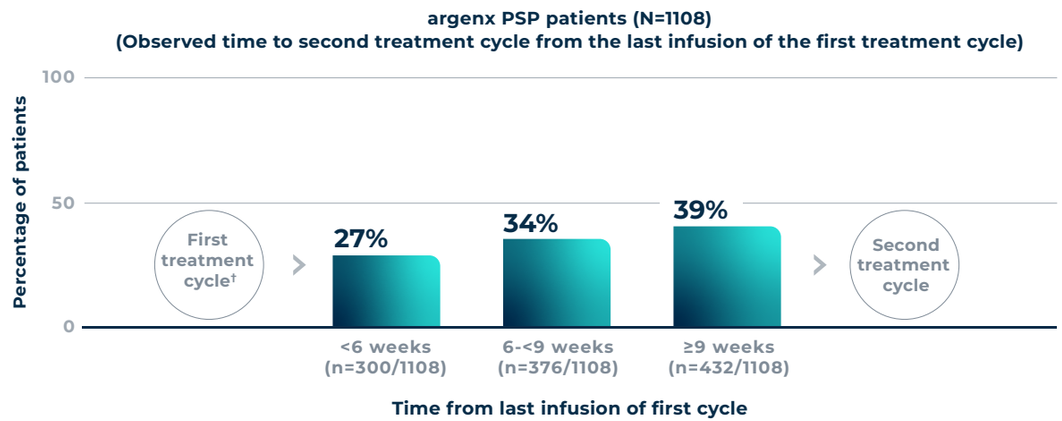
IMPORTANT SAFETY INFORMATION (cont'd)

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.

REAL-WORLD DATA

Observational real-world data: distribution of time to the second treatment cycle for patients on VYVGART[1,4]



In the ADAPT clinical trial, the minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion.

Study limitations: This real-world data comes from a retrospective, observational study self-reported by patients who were enrolled in argenx's Patient Support Program from December 2021 to January 23, 2023, and was collected by argenx-employed Nurse Case Managers. Results were validated by comparison to actual dispense data reported by specialty pharmacies. The data, which looked at patients who completed 1 treatment cycle and initiated a second cycle, should not be extrapolated to apply to subsequent cycles. This data should not be used as a substitute for conducting a clinical evaluation of each individual patient.

†Most patients completed the first treatment cycle within 21 days (1 dose every week for 4 weeks).
PSP=Patient Support Program.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed with VYVGART. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions.

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VYVGART: instructions for calculating the dose and infusion volume[1]

Below are the formulas for each step used to calculate the appropriate dose for your patient:

STEP 1: 10 mg/kg x patient weight (kg) = dose (mg)

STEP 2: Dose (mg) ÷ 20 mg/mL = drug volume (mL)

STEP 3: Drug volume (mL) ÷ 20 mL = number of vials needed per infusion (round up to whole vials)

STEP 4: 125 mL – drug volume (mL) = volume of 0.9% NaCl Injection, USP (mL)

STEP 5: Number of vials needed per infusion x 4 = number of vials per 4-week cycle

In patients weighing 265 lbs (120 kg) or more, the recommended dose is 1200 mg (3 vials) per infusion.

Prior to administration, VYVGART single-dose vials require dilution in 0.9% Sodium Chloride Injection, USP, to make a total volume of 125 mL, given to the patient in 1-hour increments. See Preparation and Administration Instructions in the Prescribing Information.

For more information, please see the DOSAGE AND ADMINISTRATION section in the full Prescribing Information.

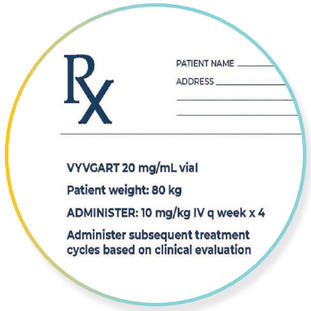
NaCl=sodium chloride.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

Example dosing calculations for VYVGART[1]



STEP 1

Calculate the recommended dose (mg)

10 mg/kg x 100 kg = 1000 mg

In patients weighing 265 lbs (120 kg) or more, the recommended dose of VYVGART is 1200 mg (3 vials) per infusion.

STEP 2

Calculate the drug volume (mL)

1000 mg ÷ 20 mg/mL = 50 mL

STEP 3

Calculate the number of vials per infusion

50 mL ÷ 20 mL = 2.5 vials **(round to 3 vials)**

Each vial contains 400 mg of efgartigimod alfa-fcab at a concentration of 20 mg/mL.

STEP 4

Calculate the volume of 0.9% NaCl Injection, USP (mL)

125 mL – 50 mL = 75 mL

(discard any unused portion of the vials)

The total volume to be administered is 125 mL over 1 hour.

STEP 5

Calculate the number of vials needed per cycle

3 vials *(rounded from 2.5)* **x 4 = 12 vials**

There are 4 weeks per treatment cycle with 1 dose administered each week.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

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Reference guide for calculating the appropriate dose of VYVGART[1]

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 1200 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)

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.

VYVGART had a demonstrated safety profile in the ADAPT clinical trial[1]

Adverse reactions in ≥5% of patients treated with VYVGART and more frequently than placebo

Adverse reaction	**VYVGART (n=84)**	**Placebo (n=83)**
Respiratory tract infection	**33%**	**29%**
Headache*	**32%**	**29%**
Urinary tract infection	**10%**	**5%**
Paraesthesia†	**7%**	**5%**
Myalgia	**6%**	**1%**

*Headache includes migraine and procedural headache.
†Paraesthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.

A higher frequency of patients who received VYVGART compared to placebo were observed to have below normal levels for white blood cell counts (12% vs 5%), lymphocyte counts (28% vs 19%), and neutrophil counts (13% vs 6%).

The majority of infections and hematologic abnormalities were mild to moderate in severity.

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

There is no information regarding the presence of VYVGART in human milk, the effects on the breastfed infant, or the effects on milk production. 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.

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VYVGART: infusion considerations[1]

Infusion recommendations

Patients should be monitored:

- During administration of VYVGART and for 1 hour after for clinical signs and symptoms of hypersensitivity reactions

If a hypersensitivity reaction occurs:

- Discontinue the infusion and institute appropriate supportive measures if needed

VYVGART may be administered in various infusion settings

- In the physician's office
- At an infusion center
- At home, with assistance from a nurse*

*Home infusions may be available for patients with insurance coverage for this service. Please contact the patient's insurance provider directly.

IMPORTANT SAFETY INFORMATION (cont'd)

Please see the full Prescribing Information.

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).

VYVGART offers broad access for your adult patients with anti-AChR antibody positive gMG

DID YOU KNOW

~85%

of US commercial and Medicare patients have a published VYVGART policy?[5†]

- Medicare Part B covers medications for indications, which are FDA approved to label
- Coverage for VYVGART depends on the terms and conditions of the patient's insurance plan

†Policy reporter data as of September 2022.
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.

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Help your patients save with VYVGART

Eligible patients **could pay as little as $0** for VYVGART through the VYVGART Co-pay Program.*

What should I tell my patients?

- The VYVGART Co-pay Program is for patients with commercial insurance and a valid prescription for VYVGART for an on-label indication
- VYVGART must be covered by patients' commercial insurance
- Patients may be reimbursed for eligible out-of-pocket costs for VYVGART and related administration costs, up to $25,000 in savings per calendar year*
- If you have enrolled your patient in My VYVGART® Path, a Nurse Case Manager can enroll them in the VYVGART Co-pay Program and answer their questions
- Patients can also be enrolled through their specialty pharmacist when they fill their prescription

*Eligible commercially insured patients may pay as little as $0 for VYVGART and may receive a maximum benefit of $25,000 per calendar year for their eligible out-of-pocket costs for the drug and drug administration. Persons residing in MA and RI are not eligible for financial assistance related to administration costs. Please see full Terms and Conditions at VYVGARTHCP.com.

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My VYVGART® Path

The committed team of Case Coordinators and Nurse Case Managers at My VYVGART Path offers:

- **Patient-specific benefit verifications**, including confirming out-of-pocket costs and prior authorization requirements
- **Screening for commercial co-pay** and other financial assistance for eligible patients
- **Referrals** to local and national myasthenia gravis resources and organizations
- **Help in connecting you with your patient's health plan** denial and appeal processes†

†Field Reimbursement Managers are not part of My VYVGART Path, but they are available to provide assistance to Case Coordinators, as needed.

Visit VYVGARTHCP.com/start or call 1-833-697-2841 for more information and assistance

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

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References: 1. VYVGART. Prescribing information. argenx US Inc; 2022. **2.** Wolfe GI et al. *J Neurol Sci*. 2021;430:118074. doi:10.1016/j.jns.2021.118074 **3.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **4.** Qi C et al. Poster presented at: 45th Annual Carrell-Krusen Neuromuscular Symposium. February 23-24, 2023. Dallas, TX. **5.** Data on file, argenx US Inc. March 2023.

Please see the full Prescribing Information.

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Visit VYVGARTHCP.com/dosing to find out more

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