Not actual size.

FOR YOUR ADULT PATIENTS WITH **ANTI-AChR ANTIBODY POSITIVE gMG**

Navigating dosing and administration

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

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

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.

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.

VYVGART Hytrulo and VYVGART: 2 options for ongoing treatment[1,2]

Recommended dose and dose schedules from Prescribing Information:

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

~30-90–SECOND SC INJECTION*
PER WEEK **FOR 4 WEEKS**
(1,008 mg efgartigimod alfa/11,200 units hyaluronidase)
fixed dose

The recommended dose of **VYVGART Hytrulo** is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase), given in treatment cycles of once-weekly subcutaneous injections for 4 weeks.

VYVGART: **1 TREATMENT CYCLE**[2]

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[1,2]

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

*Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.[1]
†In patients weighing 265 lbs (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.[2]
‡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.[1,3]
IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS
Infection
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).

An example approach:

Based on the most commonly observed schedule from a post-hoc analysis of ADAPT-SC+ and ADAPT+[4§‖]

CYCLES 1-3

4 WEEKS **ON** THERAPY

4 WEEKS **OFF** THERAPY[¶]

FOR THE FIRST **3** TREATMENT CYCLES[#]

CYCLES 4+

ADJUSTING TIME OFF THERAPY BASED ON CLINICAL EVALUATION

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

For subsequent cycles, **continue** evaluating the appropriate time off therapy based on clinical evaluation.[4]

Limitations: The distribution of average cycle duration in ADAPT-SC+ and ADAPT+ 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-SC+ and ADAPT+ were single-arm, open-label studies evaluating the long-term safety and tolerability of VYVGART Hytrulo and VYVGART.[5,6]
‖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.[4]
¶Four weeks off starts after the last injection or infusion of the most recent cycle.[4]
#A cycle consists of 4 once-weekly doses over 22 days.[4]

IMPORTANT SAFETY INFORMATION (cont'd)
Infection (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). The majority of infections and hematologic abnormalities were mild to moderate in severity.

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Injection for Intravenous Use
400 mg/20 mL vial

Preparation instructions for **VYVGART Hytrulo**[1]

Supplies needed for administration	
• Alcohol swabs	• Adhesive bandage
• One 10 mL syringe	• One FDA-cleared sharps container
• One winged infusion set 25G x 12 inches	• One 18G transfer needle (2-inch length)
• One sterile gauze	

It is important to use an aseptic technique when preparing and administering VYVGART Hytrulo.

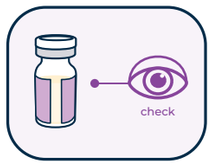
Store **VYVGART Hytrulo** vials refrigerated at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light until time of use. Do not freeze. Do not shake.

STEP 1

Take the vial out of the refrigerator at least 15 minutes before injecting, and allow it to reach room temperature. Do not use external heat sources.

STEP 2

Visually inspect the solution to ensure it is yellowish, clear to opalescent. Do not use if opaque particles or other foreign particles are present.



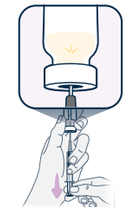
IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

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.

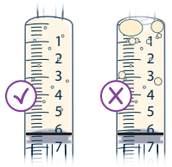
STEP 3

Withdraw the entire contents of **VYVGART Hytrulo** from the vial using a polypropylene syringe and an 18G stainless steel transfer needle.



STEP 4

Remove large air bubbles if present.



VYVGART Hytrulo does not contain preservatives and must be administered immediately after preparation

IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

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.

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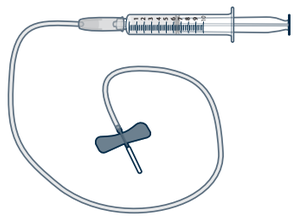
Administration instructions for VYVGART Hytrulo[1]

VYVGART Hytrulo is administered with a winged infusion set 25G, 12-inch tubing, made of polyvinyl chloride (PVC), and a maximum priming volume of 0.4 mL.

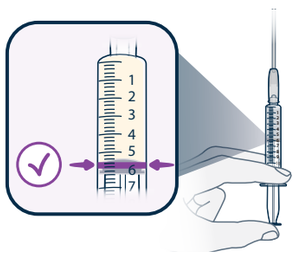
STEP 1

Remove the transfer needle from the syringe and connect the syringe to the winged infusion set.



STEP 2

Fill the tubing of the winged infusion set by gently pressing the syringe plunger until the plunger is at 5.6 mL. There should be solution at the end of the winged infusion set needle.



IMPORTANT SAFETY INFORMATION (cont'd)

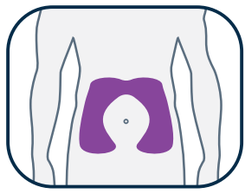
Immunization (cont'd)

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.

STEP 3

Choose an injection site on the abdomen at least 2-3 inches from the navel. Do not inject on areas where the skin is red, bruised, tender, or hard, or into areas where there are moles or scars.

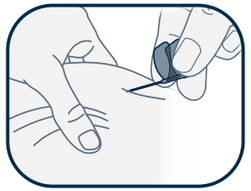
Rotate injection sites for subsequent administrations.



STEP 4

Inject **VYVGART Hytrulo** subcutaneously into an area of pinched skin at an angle of about 45 degrees over 30-90 seconds.

Localized injection site reactions may occur after **VYVGART Hytrulo** is administered.



IMPORTANT SAFETY INFORMATION (cont'd)

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, and did not lead to treatment discontinuation.

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

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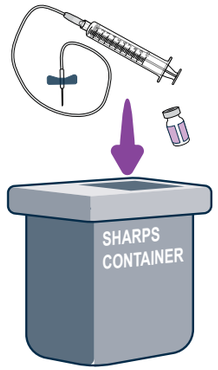
Administration instructions for **VYVGART Hytrulo** (cont'd)[1]

STEP 5

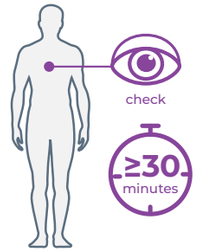
Once administration is complete, discard any solution remaining in the vial, the syringe, and the winged infusion set.



STEP 6

Healthcare professionals should monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.

If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.



Potential injection site reactions[1,2,7,8]

In ADAPT-SC, injection site reactions occurred in 38% of patients receiving **VYVGART Hytrulo**. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria.

In ADAPT-SC and its open-label extension (n=168):

- 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 of injection site reactions decreased with each subsequent cycle
  - Cycle 1: 34.1% (n=56); cycle 2: 16.9% (n=24); cycle 3: 13.3% (n=14); and cycle 4: 11.8% (n=8)*

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with **VYVGART Hytrulo** or **VYVGART**. Urticaria was also observed in patients treated with **VYVGART Hytrulo**. 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.

*Interim results presented April 2023. The ADAPT-SC+ Open-label Extension study is still ongoing.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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. Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, for clinical signs and symptoms of hypersensitivity reactions.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

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

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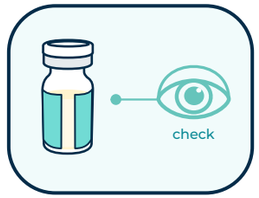
400 mg/20 mL vial

Preparation instructions for VYVGART[2]

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.

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-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.

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.

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)

Infusion-Related Reactions (cont'd)

If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy.

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) Subcutaneous Injection 180 mg/mL and 2000 U/mL vial

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

Administration instructions for VYVGART[2]

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)

Infusion-Related Reactions (cont'd)

Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO 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.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Dose calculation and infusion volume of **VYVGART**[2]

STEP 1

Calculate the recommended dose (mg) of VYVGART

10 mg/kg x patient weight (kg) = dose (mg)

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

STEP 2

Calculate the drug volume (mL)

Dose (mg) ÷ 20 mg/mL = drug volume (mL)

STEP 3

Calculate the number of vials

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

STEP 4

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

125 mL - drug volume (mL) = volume of 0.9% NaCl Injection, USP (mL)

Dosing Calculator

Provided is a reference guide for calculating the appropriate dose of **VYVGART**:

Patient weight kg (lb)	**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)	**1,000**	**50**	**3**	**12**
105 (231)	**1,050**	**52.5**	**3**	**12**
110 (243)	**1,100**	**55**	**3**	**12**
115 (254)	**1,150**	**57.5**	**3**	**12**

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

Calculate your patient's appropriate dose
For your ease and convenience when it comes to dosing and administration, use our interactive dosing calculator

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

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.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

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.

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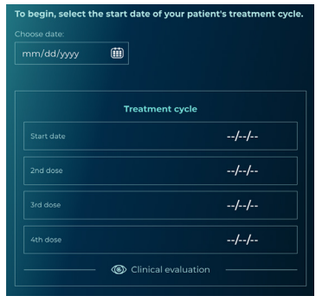
VYVGART Hytrulo and VYVGART Dosing Resources

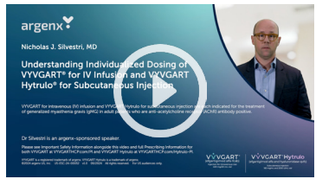
Access available resources to help support your practice:



Dosing Schedule Tool

This tool may help you plan the dates of your patient's upcoming treatment cycle(s) for **VYVGART Hytrulo** or **VYVGART**. Remember, subsequent treatment cycles should be administered based on clinical evaluation.[1,2]

Learn more



Dosing Video

Hear an expert discuss the dosing of **VYVGART Hytrulo** and **VYVGART**.

Watch now

Field Clinical Educator

Ask your representative about registered nurses who can provide education on argenx products, including dosing and administration

Hypersensitivity and infusion-related reactions[1,2]:

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with **VYVGART Hytrulo** or **VYVGART**. Urticaria was also observed in patients treated with **VYVGART Hytrulo**. 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.

Pregnancy Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to **VYVGART Hytrulo** and **VYVGART** during pregnancy. Healthcare providers and patients may call 1-855-272-6524 or go to https://www.vyvgartpregnancy.com to enroll in or to obtain information about the registry.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy (cont'd)

Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

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)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

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

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.

WARNINGS AND PRECAUTIONS

Infection

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, and did not lead to treatment discontinuation. 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. Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, 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.

Infusion-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-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO 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 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).

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024. **2.** VYVGART. Prescribing information. argenx US Inc; 2024. **3.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **4.** Data on file. REF-02349. argenx US Inc. November 2023. **5.** ClinicalTrials.gov. NCT03770403. Accessed November 14, 2024. https://clinicaltrials.gov/study/NCT03770403 **6.** ClinicalTrials.gov. NCT04818671. Accessed November 14, 2024. https://clinicaltrials.gov/study/NCT04818671 **7.** Howard JF Jr et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 22-27, 2023. Boston, MA. **8.** Howard JF Jr et al. *Neurotherapeutics*. 2024;21(5):1-12. doi:10.1016/j.neurot.2024.e0037

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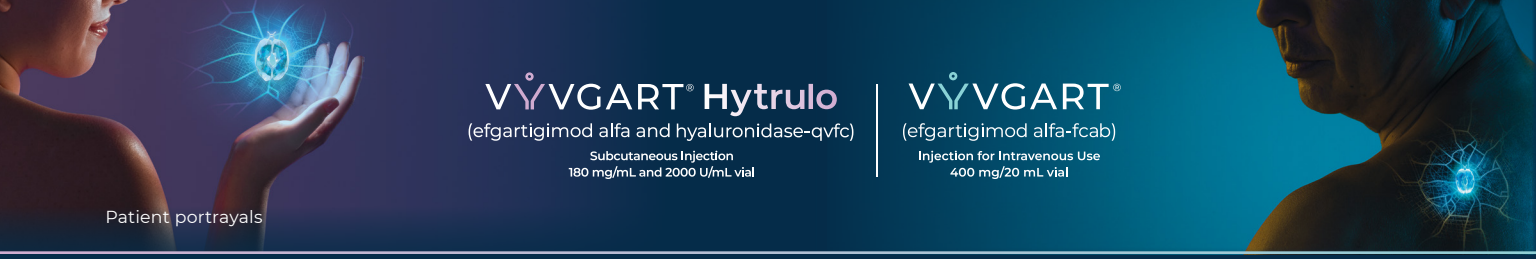

VYVGART for IV infusion and **VYVGART Hytrulo** for SC injection are the combined **#1 prescribed FDA-approved biologic treatments** for adult patients with anti-AChR antibody positive gMG*

Discover dosing and administration at
vyvgarthcp.com/gmg/dosing

*Based on IQVIA LAAD from January 2023 to April 2024. Data is based on validated claims of VYVGART for IV infusion, VYVGART Hytrulo for SC injection, and other biologics that have been approved by the FDA for the treatment of adults with anti-AChR antibody positive gMG. Patients who were prescribed more than one of the biologics in this data set were counted for each biologic prescribed.

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

INDICATION

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