NOW AVAILABLE | VYVGART HYTRULO® PREFILLED SYRINGE FOR SELF-INJECTION

Dosing and administration

for your adult patients with anti-AChR antibody positive gMG[1]

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

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**: 3 administration options to use at home, in office, or at an infusion center[1,2]

1 TREATMENT CYCLE = 1 DOSE PER WEEK FOR 4 WEEKS

Recommended dose and dose schedules from Prescribing Information:

Not actual size.

VYVGART Hytrulo
Single-dose prefilled syringe

Administered by a patient or caregiver*

~20-30–SECOND SC SELF-INJECTION†
(1,000 mg efgartigimod alfa/10,000 units hyaluronidase, fixed dose)

The recommended dose of **VYVGART Hytrulo** prefilled syringe is 1,000 mg/10,000 units (1,000 mg efgartigimod alfa/10,000 units hyaluronidase), given in treatment cycles of once-weekly SC injections for 4 weeks.

Not actual size.

VYVGART Hytrulo
Single-dose vial

HCP administered

~30-90–SECOND SC INJECTION†
(1,008 mg efgartigimod alfa/11,200 units hyaluronidase, fixed dose)

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

Not actual size.

VYVGART
Single-dose vial

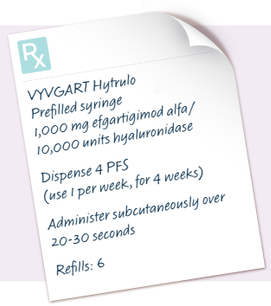
HCP administered

1-HOUR IV INFUSION‡
(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.

For each option, 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]



Prescribing the prefilled syringe

Order the 4-pack for 4 weeks of treatment and fewer deliveries from the specialty pharmacy.

Use your clinical judgment to determine the appropriate amount of refills for your patient.

Example prescription only. Not to be used for reference.

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).

*After proper instruction on SC injection technique, a patient or caregiver may inject VYVGART Hytrulo prefilled syringe. See Prescribing Information.[1]
†Refers to actual subcutaneous injection time. 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.[1]
‡Refers to actual intravenous infusion time. Monitor patients during 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.[2]
§In patients weighing 265 lb (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.[2]
HCP=healthcare professional; IV=intravenous; SC=subcutaneous.

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)

Patient portrayal

Open up their world to **VYVGART Hytrulo** prefilled syringe for self-injection[1]

A new way to administer VYVGART Hytrulo that can fit into their lives, including at home[1]

Fast, ~20-30–second self-injection
Refers to actual subcutaneous injection time of **VYVGART Hytrulo prefilled syringe**. Monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a hypersensitivity reaction occurs, the patient should seek medical attention.[1]

100% of patients with gMG and caregivers successfully used the prefilled syringe and interacted with the associated labeling, packaging, and instructional materials across 2 human factors studies (15 patients and 15 caregivers of gMG patients). All participants were able to follow the Instructions for Use and prepare and administer the dose into the simulated injection pad unaided.[3]*

Patients and/or caregivers will receive in-person injection training until ready to inject†

*Human factors studies evaluated participants' ability to follow injection instructions and successfully prepare the product in a simulated-use environment. During the unaided injection, 2 use errors and one close call occurred. The use errors were participants not putting the product back into the original packaging before putting into the refrigerator, and the close call was a participant removing the needle cap at the incorrect time. Performance of critical tasks did not result in any patterns of use errors, close calls, or difficulties that would lead to patient harm (including compromised medical care). Findings were based on performance, observed behaviors, subjective feedback, and human factors analyses, and therefore were not traditionally statistically analyzed.[3]
†After proper instruction on subcutaneous injection technique, a patient or caregiver may inject VYVGART Hytrulo prefilled syringe. See Prescribing Information.[1]
gMG=generalized myasthenia gravis.

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

An example approach to dosing with **VYVGART Hytrulo** and **VYVGART**

Based on the most commonly observed schedule from a post-hoc analysis of ADAPT-SC+ and ADAPT+‡§

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)

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.

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)

Preparing **VYVGART Hytrulo** prefilled syringe[1]

The **VYVGART Hytrulo** prefilled syringe is administered subcutaneously. Each prefilled syringe contains 5 mL of solution.[1]

Supplies needed for administration

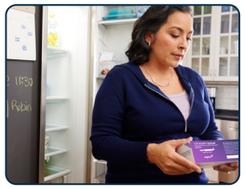
- Safety needle (25G, 5/8-inch length, thin wall)
- One alcohol swab
- One FDA-cleared sharps disposal container
- One sterile gauze and/or bandage (as needed)

Store **VYVGART Hytrulo** prefilled syringe 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.[1]

If needed, prefilled syringes may be stored at room temperature up to 30 °C (86 °F) in the original carton for a single period of up to 30 days after removing from the refrigerator or until expiration date on the carton, whichever occurs first. Record the date removed from the refrigerator on the carton.[1]

STEP 1

Remove 1 prefilled syringe from the refrigerator and place any remaining syringes back in the refrigerator.



STEP 2

Check the expiration date on the prefilled syringe label. Do not use the prefilled syringe if the expiration date has passed.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization (cont'd)

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

The liquid medicine should look clear to yellowish in color. Do not use the prefilled syringe if medicine is discolored or contains particles.

STEP 4

Place the syringe on a clean, flat surface and let it warm to room temperature for at least 30 minutes before injecting. Do not attempt to warm the prefilled syringe in any other way.

STEP 5

Wash hands with soap and water. Carefully remove the needle from the package. Bend the prefilled syringe cap to one side to remove it from the syringe, then attach the needle to the syringe by twisting it on (clockwise) until you feel resistance.

Please review the detailed Instructions for Use and the Preparation and Administration Instructions in Section 2.5 of the VYVGART Hytrulo Prescribing Information.

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.

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)

Administering **VYVGART Hytrulo** prefilled syringe[1]

STEP 1

Choose an injection site on the abdomen at least 2 inches away from the belly button (navel). Do not inject into a vein; into skin that is irritated, red, bruised, infected, tender, or hard; or into areas where there are moles or scars. Rotate injection sites for subsequent administration.

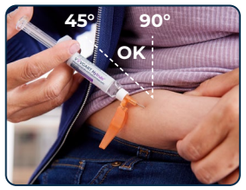
Clean the chosen injection site with an alcohol swab and let it air dry.

STEP 2

Insert the full length of the needle into an area of pinched skin at a 45 to 90 degree angle. Slowly press the thumb pad all the way down. It will take approximately 20-30 seconds to inject all of the liquid medicine.*

If there is a small amount of blood or liquid at the injection site, press gauze over the site until bleeding stops.

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



*Refers to actual subcutaneous injection time of VYVGART Hytrulo. Monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a reaction occurs, the patient should seek medical attention.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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.

Post-injection of **VYVGART Hytrulo** prefilled syringe[1]

STEP 1

Once administration is complete, discard the used prefilled syringe with the needle attached.

STEP 2

Monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a **hypersensitivity reaction** occurs, the patient should seek medical attention.

When using the prefilled syringe, VYVGART Hytrulo can be self-injected by the patient, or administered by a caregiver or healthcare professional. VYVGART Hytrulo is for subcutaneous use only. Do not administer intravenously.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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.

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)

Preparing **VYVGART Hytrulo** single-dose vial[1]

Supplies needed for administration

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

It is important to use an aseptic technique when preparing and administering VYVGART Hytrulo.[1]

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.[1]

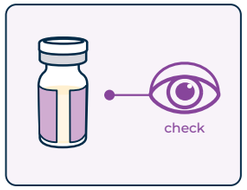
If needed, unopened vials may be stored in the original carton for up to 3 days at room temperature at 20 °C to 25 °C (68 °F to 77 °F) for a single period before administration or returned to refrigeration. Do not store the vial at room temperature more than one time. Record the date removed from and the date returned to the refrigerator on the carton.[1]

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.



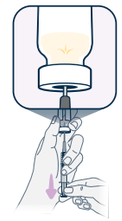
IMPORTANT SAFETY INFORMATION (cont'd)

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.

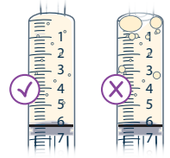
STEP 3

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.

Please review Preparation and Administration Instructions in Section 2.5 of the VYVGART Hytrulo 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. 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.

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

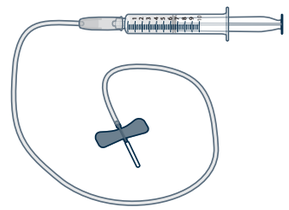
VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) | VYVGART® (efgartigimod alfa-fcab)

Administering **VYVGART Hytrulo** single-dose vial[1]

VYVGART Hytrulo is administered with a winged infusion set made of polyvinyl chloride (PVC), 25G, 12-inch tubing, and a maximum priming volume of 0.4 mL[1]

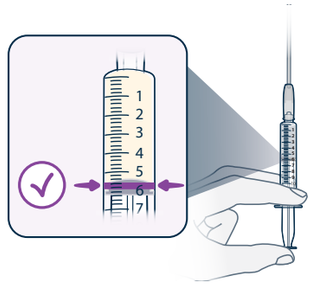
STEP 1

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)

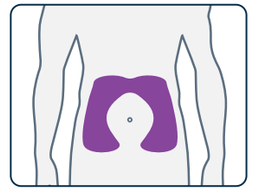
Infusion/Injection-Related Reactions

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.

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.

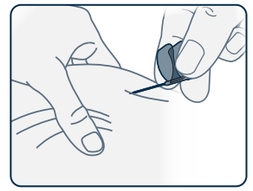


STEP 4

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.

If there is a small amount of blood or liquid at the injection site, press gauze over the site until bleeding stops.



IMPORTANT SAFETY INFORMATION (cont'd)

Infusion/Injection-Related Reactions (cont'd)

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.

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

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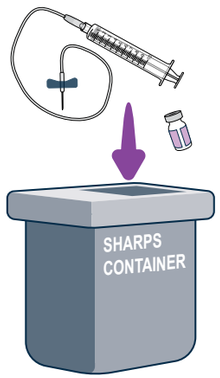
STEP 5

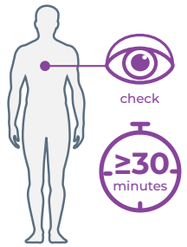
Once administration is complete, discard any solution remaining in the vial, the syringe, and the winged infusion set.



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.



Please review Preparation and Administration Instructions in Section 2.5 of the VYVGART Hytrulo Prescribing Information.

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. 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.

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.[1]

In ADAPT-SC and its open-label extension (n=168)[1]:

- 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)[7,8]*

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 and occurred within one hour to three weeks of administration.[1,2]

VYVGART Hytrulo can cause anaphylaxis and hypotension leading to syncope, as well as infusion/injection-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration with **VYVGART** and led to infusion discontinuation and in some cases to permanent treatment discontinuation. If a hypersensitivity reaction occurs with **VYVGART Hytrulo**, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention. If a severe infusion/injection-related reaction occurs with **VYVGART Hytrulo**, initiate appropriate therapy.[1,2]

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

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.

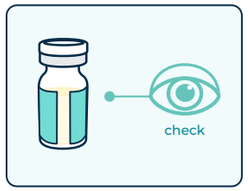
Please see additional Important Safety Information throughout and full Prescribing Information for VYVGART Hytrulo and full Prescribing Information for VYVGART.

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

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[2]

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.[2]



Use an aseptic technique when preparing the **VYVGART** diluted solution for intravenous infusion. Each vial is for single-dose only. Discard any unused portion.[2]

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 vial(s).

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)

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.

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 (polyolefin bags), and with PE, PVC, EVA, or polyurethane/polypropylene infusion lines.

Storing VYVGART after dilution[2]:

VYVGART does not contain preservatives. Administer immediately after dilution and complete the infusion within 4 hours of dilution.[2]

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.[2]

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

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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)

Administration instructions for **VYVGART**[2]

VYVGART should be administered via intravenous infusion by a healthcare professional[2]

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[2]

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

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation (cont'd)

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.

Hypersensitivity reactions and infusion/injection-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.[1,2]

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.[2]

VYVGART Hytrulo can cause anaphylaxis and hypotension leading to syncope, as well as infusion/injection-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration with **VYVGART** and led to infusion discontinuation and in some cases to permanent treatment discontinuation. If a hypersensitivity reaction occurs with **VYVGART Hytrulo**, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention. If a severe infusion/injection-related reaction occurs with **VYVGART Hytrulo**, initiate appropriate therapy.[1,2]

Pregnancy Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to **VYVGART Hytrulo** or **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.[1,2]

IMPORTANT SAFETY INFORMATION (cont'd)

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).

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)

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 vial[s])

STEP 4

Calculate the volume of 0.9% Sodium Chloride (NaCl) Injection, USP (mL)
125 mL - drug volume (mL) = volume of 0.9% NaCl Injection, USP (mL)

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

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

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.

Dosing calculator

Provided is a reference guide for calculating the appropriate dose of **VYVGART**[2]:

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.[2]

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)

CONTRAINDICATIONS (cont'd)

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

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

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.

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

NOW AVAILABLE | VYVGART HYTRULO® PREFILLED SYRINGE FOR SELF-INJECTION

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

VYVGART®
(efgartigimod alfa-fcab)

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 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.

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.

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2025. **2.** VYVGART. Prescribing information. argenx US Inc; 2024. **3.** Data on file. REF-03778. argenx US Inc. January 2025. **4.** Data on file. REF-02349. argenx US Inc. November 2023. **5.** ClinicalTrials.gov. NCT03770403. Accessed February 19, 2025. https://clinicaltrials.gov/study/NCT03770403 **6.** ClinicalTrials.gov. NCT04818671. Accessed February 19, 2025. 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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