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

VYVGART HYTRULO

Dosing and Administration Guide

Give your adult patients with anti-AChR antibody positive gMG another option for ongoing treatment with **VYVGART Hytrulo**, a ready-to-use solution for injection.[1]*

*No dilution required. Allow for appropriate storage, preparation, and setup time before use.
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.
Patient portrayal

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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

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

Recommended dose and dose schedule 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.

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

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

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

†Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.[1]

MG-ADL=Myasthenia Gravis Activities of Daily Living; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNING AND PRECAUTIONS

Infection

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 infections (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).

An example approach:

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

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**.

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

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

‡ADAPT+ and ADAPT-SC+ were single-arm, open-label studies evaluating the long-term safety and tolerability of VYVGART and VYVGART Hytrulo.[4,5]

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

‖Four weeks off starts after the last injection of the most recent cycle.[3]

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

IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay VYVGART HYTRULO administration in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART HYTRULO until the infection has resolved.

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

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

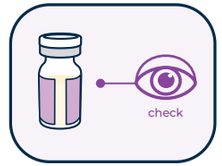
IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

Immunization with vaccines during VYVGART HYTRULO 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 HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

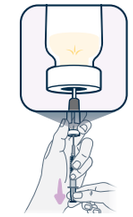
STEP 2

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



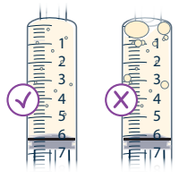
STEP 3

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)

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. 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.

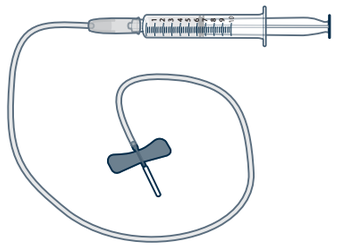
VYVGART® Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

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.

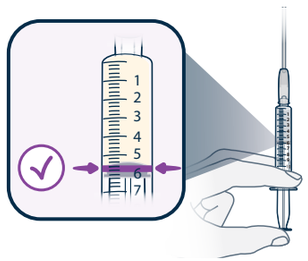
STEP 1

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)

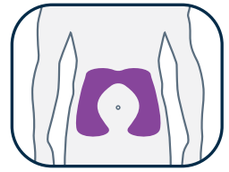
Hypersensitivity Reactions (cont'd)

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 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.

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.

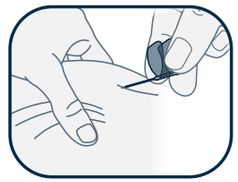
Rotate injection sites for subsequent administrations.



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)

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.

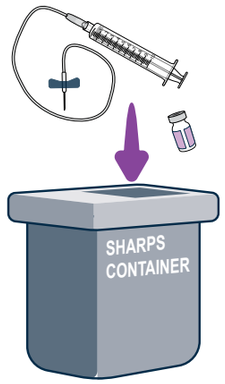
Please see additional Important Safety Information throughout and full Prescribing Information.

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

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

STEP 5

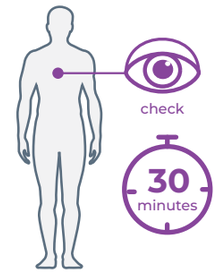
Once administration is complete, discard any solution remaining in the vial, the syringe, and the winged infusion set.



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.



IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-Related Reactions (cont'd)

If a severe infusion-related reaction occurs, initiate appropriate therapy. Consider the risks and benefits of readministering 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.

Potential injection site reactions[1,6]

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)

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. 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.

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

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infection

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 infections (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 VYVGART HYTRULO administration in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART HYTRULO until the infection has resolved.

Immunization

Immunization with vaccines during VYVGART HYTRULO 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 HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. 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 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.

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, initiate appropriate therapy. Consider the risks and benefits of readministering 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 HYTRULO 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 HYTRULO in utero.

Lactation

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

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

For more information on dosing and administration for **VYVGART Hytrulo**, visit **VYVGARTHCP.com/hytrulo-dosing**

Not actual size.

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2023. **2.** VYVGART. Prescribing information. argenx US Inc; 2023. **3.** Data on file, argenx US Inc. January 2024. **4.** ClinicalTrials.gov. NCT03770403. Accessed December 12, 2023. https://clinicaltrials.gov/study/NCT03770403 **5.** ClinicalTrials.gov. NCT04818671. Accessed December 12, 2023. https://clinicaltrials.gov/study/NCT04818671 **6.** Howard JF Jr et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 22-27, 2023. Boston, MA.

argenx

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