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

VYVGART Hytrulo Administration Guide

Give your adult patients with anti-AChR antibody positive gMG another option 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

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 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 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: ongoing treatment with an individualized dosing schedule based on clinical evaluation of patient needs[1]

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

1 treatment cycle =
1 injection per week for 4 weeks
(1,008 mg efgartigimod alfa/11,200 units hyaluronidase)
~30-90–second injection*

Subsequent treatment cycles
Administer subsequent treatment cycles based on clinical evaluation

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

*Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.

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.

It may help to schedule subsequent cycles in advance.[2]

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

Not actual size.

Patients should be advised to complete age-appropriate vaccinations according to immunization guidelines prior to initiation of a new treatment cycle with VYVGART Hytrulo. Vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART Hytrulo. No specific vaccinations were required in the ADAPT-SC clinical trial inclusion criteria[1,3]

gMG=generalized myasthenia gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization (cont'd)

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

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

It is important to use an aseptic technique when preparing and administering VYVGART Hytrulo. Each vial is for one-time use only. Avoid exposure to direct sunlight.

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.

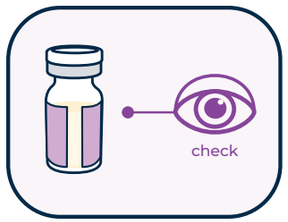
STEP 1

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.



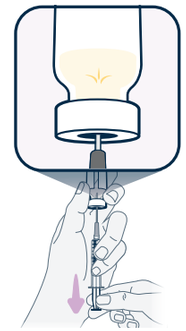
IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO and efgartigimod alfa-fcab. Urticaria was also observed in patients treated with VYVGART HYTRULO. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients for at least 30 minutes after administration for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, institute appropriate supportive measures if needed.

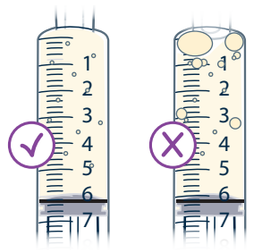
STEP 3

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)

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.

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

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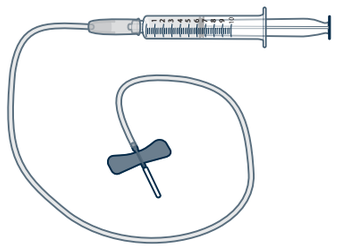
Administration instructions for **VYVGART Hytrulo**[1]

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.

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	

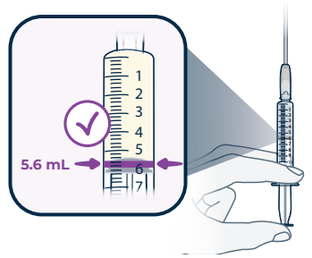
STEP 1

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



STEP 2

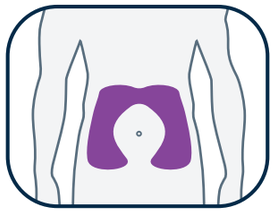
Fill the tubing of the winged infusion set by gently pressing the syringe plunger until the plunger is at 5.6 mL. There should be solution at the end of the winged infusion set needle.



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.

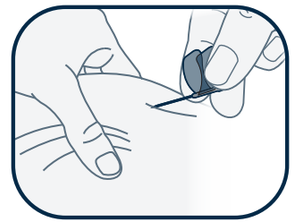
Rotate injection sites for subsequent administrations.



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)

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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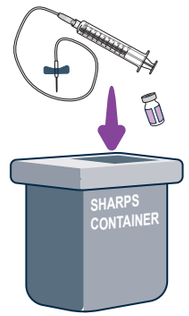
Administration instructions for **VYVGART Hytrulo** (cont'd)[1]

STEP 5

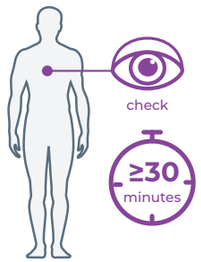
Once administration is complete, discard any solution remaining in the vial, the syringe, and the winged infusion set.



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.



Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART Hytrulo and VYVGART® (efgartigimod alfa-fcab). Urticaria was also observed in patients treated with VYVGART Hytrulo.

- In clinical trials, hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Potential injection site reactions[1,3]

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)*

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

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 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).

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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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 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 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

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ADVERSE REACTIONS

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USE IN SPECIFIC POPULATIONS

Pregnancy

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

INDICATION

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References: 1. VYVGART Hytrulo. Prescribing Information. argenx US Inc; 2023. **2.** VYVGART. Prescribing information. argenx US Inc; 2022. **3.** Casey J et al. Poster presented at: 27th International Hybrid Annual Congress of the World Muscle Society; October 2022; Halifax, Nova Scotia, Canada.

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