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

VYVGART Hytrulo
Frequently Asked Questions

Answers to common questions about treatment with **VYVGART Hytrulo**

Fab=fragment, antigen-binding; Fc=fragment, crystallized; IgG=immunoglobulin G.

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).

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

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How does VYVGART Hytrulo work?

VYVGART Hytrulo is a coformulation of efgartigimod alfa, which is the same active ingredient in VYVGART® (efgartigimod alfa-fcab), and hyaluronidase. Efgartigimod alfa is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG.[1,2]

Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. This effect is transient, and permeability of the subcutaneous tissue is restored within 24 to 48 hours.[1]

Fc=fragment, crystallized; IgG=immunoglobulin G.

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. 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.

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What was the design of the ADAPT-SC clinical trial?

ADAPT-SC was a 10-week, phase 3, multicenter, randomized, open-label, parallel-group trial conducted in adult patients with gMG to evaluate the pharmacodynamic (PD) effect of VYVGART Hytrulo compared to VYVGART® (efgartigimod alfa-fcab) in adult patients with gMG. A total of 110 patients were randomized and received 1 cycle of either VYVGART Hytrulo 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) (n=55) or VYVGART at 10 mg efgartigimod alfa-fcab/kg (n=55) once weekly for 4 weeks.[1,3]

All patients were on stable doses of gMG therapy prior to screening, including AChE inhibitors, steroids, or NSISTs, either in combination or alone. In addition to PD, the safety of VYVGART Hytrulo was also assessed.[3*]

How was FDA approval determined for VYVGART Hytrulo?

The ADAPT trial established the effectiveness of VYVGART for IV infusion in the treatment of gMG in adults who are anti-AChR antibody positive. The ADAPT-SC trial established that VYVGART Hytrulo and VYVGART showed a similar PD effect in reduction of AChR-Ab levels in adult patients with gMG who are anti-AChR antibody positive, which established the efficacy of VYVGART Hytrulo.[†‡]

*MG-ADL total score of ≥5 required at screening.
†The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and $AEC_{0\text{-}4w}$ (area under the effect-time curve from time 0 to 4 weeks post dose) were within the range of 80% to 125%, indicating no clinically significant difference between the two formulations.
‡Seven days after the fourth IV or SC administration.
AChE=acetylcholinesterase; AChR=acetylcholine receptor; AChR-Ab=acetylcholine receptor antibody; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; IV=intravenous; NSIST=nonsteroidal immunosuppressive therapy.

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.

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What were some of the additional endpoints and analyses of the ADAPT-SC clinical trial?

The secondary endpoint was the change in AChR-Ab levels over time with VYVGART Hytrulo and VYVGART® (efgartigimod alfa-fcab) in the anti-AChR antibody positive population.[1]

A post-hoc analysis observed MG-ADL data for Minimal Symptom Expression (MSE) with VYVGART Hytrulo and VYVGART in the anti-AChR antibody positive population.[4]

Exploratory endpoints were MG-ADL and QMG response data for VYVGART Hytrulo and VYVGART in the anti-AChR antibody positive population.[4]

AChR=acetylcholine receptor; AChR-Ab=acetylcholine receptor antibody; MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis.

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.

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What are the most common adverse reactions for VYVGART Hytrulo?

The overall safety profile of VYVGART Hytrulo, except for a higher rate of injection site reactions, was consistent with the proven safety profile of VYVGART® (efgartigimod alfa-fcab).

In the ADAPT clinical trial, the most common adverse reactions for VYVGART-treated patients were respiratory tract infection, headache, and urinary tract infection. Additionally, a higher frequency of patients who received VYVGART compared to placebo were observed to have below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts that were mild to moderate in severity.[2]

In the ADAPT-SC clinical trial, the most common adverse reactions for VYVGART Hytrulo-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of patients receiving VYVGART Hytrulo.[1]

What should I know about injection site and hypersensitivity reactions with VYVGART Hytrulo?

Injection site reactions such as injection site rash, erythema, pruritus, bruising, pain, and urticaria were observed in 38% of patients receiving VYVGART Hytrulo in the ADAPT-SC clinical trial. According to the ADAPT-SC clinical trial and its open-label extension that included data from 168 patients, 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.[1]

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.

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Most injection site reactions occurred during the first treatment cycle, and the incidence 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).[1]*

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART Hytrulo or 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.[1]

What do I do if my patient is currently experiencing injection site reactions?

While there was no specific requirement for premedication prior to treatment with VYVGART Hytrulo in the ADAPT-SC clinical trial, you can institute supportive measures per clinical judgment. Healthcare professionals should monitor for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.[1]

You should also advise staff to take the VYVGART Hytrulo vial out of the refrigerator at least 15 minutes before injecting to allow it to reach room temperature. They should choose a different spot each time they inject (ie, rotate the site) to reduce discomfort.[1]

Was premedication used in the clinical trial prior to injection of VYVGART Hytrulo?

There was no specific requirement for premedication prior to treatment with VYVGART Hytrulo in the ADAPT-SC clinical trial.[1]

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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

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.

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What is the dosing schedule for VYVGART Hytrulo?

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

It may help to schedule subsequent cycles in advance.

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.

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

Where can VYVGART Hytrulo be administered?

VYVGART Hytrulo offers flexibility in meeting patients' needs with subcutaneous administration in a healthcare professional's office, infusion center or outpatient hospital clinic, or at home with assistance from a nurse.[1]*

*Home injections may be available for patients with insurance coverage for this service. Please contact the patient's insurance provider directly.
gMG=generalized myasthenia gravis.

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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Will my staff need training to administer VYVGART Hytrulo? If so, what does this look like?

argenx will utilize its specialty pharmacy network to ensure appropriate training and support. Our program provides comprehensive nurse training and ancillary supplies via specialty pharmacies and external partners.

What is the volume of VYVGART Hytrulo? Does it require multiple injections?

VYVGART Hytrulo is delivered as a single 5.6 mL injection and includes 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase (180 mg/2,000 units per mL). It is administered subcutaneously in treatment cycles of once-weekly injections for 4 weeks. An injection typically takes ~30 to 90 seconds.[1]*

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

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

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. 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.

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How does VYVGART Hytrulo allow for an individualized treatment approach?

VYVGART Hytrulo offers another way to deliver individualized dosing based on clinical evaluation of your patients' needs. It is recommended that VYVGART Hytrulo be administered subcutaneously in treatment cycles of once-weekly injections for 4 weeks.[1]

It may help to schedule subsequent cycles in advance.

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.

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

gMG=generalized myasthenia gravis.

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. **4.** Data on file, argenx US Inc. June 2023.

IMPORTANT SAFETY INFORMATION (cont'd)

Please see the full Prescribing Information.

You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

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