

VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qvfc)

**FOR ADULTS WITH CIDP OR ANTI-AChR
ANTIBODY POSITIVE gMG¹**

VYVGART Hytrulo Prefilled Syringe
for Subcutaneous Self-injection:

Frequently Asked Questions



Not actual size.

AChR=acetylcholine receptor; CIDP=chronic inflammatory demyelinating polyneuropathy; gMG=generalized myasthenia gravis.

INDICATION

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

VYVGART HYTRULO[®] (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

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](#) for VYVGART Hytrulo.

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Q: What is the VYVGART Hytrulo prefilled syringe?

The VYVGART Hytrulo prefilled syringe is a 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase dose per 5 mL subcutaneous injection that can be administered by a patient or caregiver. The prefilled syringe contains the same active ingredients as the VYVGART Hytrulo vial. The prefilled syringe injection takes approximately 20-30 seconds.^{1*}

Q: What types of patients are right for treatment with the VYVGART Hytrulo prefilled syringe?

The VYVGART Hytrulo prefilled syringe may be right for patients who prefer administration at home. The VYVGART Hytrulo prefilled syringe may be administered by patients and/or caregivers after proper instruction in subcutaneous injection technique.¹

Q: Where can patients have the VYVGART Hytrulo prefilled syringe administered?

The VYVGART Hytrulo prefilled syringe is a treatment option that allows subcutaneous administration at home.¹ With proper injection training, patients and/or caregivers using the prefilled syringe may administer VYVGART Hytrulo at home. Injection training will continue until the patient or caregiver is comfortable administering with the prefilled syringe.

Frequently Asked Questions

What is the VYVGART Hytrulo prefilled syringe?

What types of patients are right for treatment with the VYVGART Hytrulo prefilled syringe?

Where can patients have the VYVGART Hytrulo prefilled syringe administered?

*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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infections

VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 in patients with gMG 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).

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.



Q: What studies have been conducted for the VYVGART Hytrulo prefilled syringe?

Multiple studies of the VYVGART Hytrulo prefilled syringe assessed bioequivalence and patients' ability to successfully prepare and administer the prefilled syringe.

100% of patients with CIDP or gMG and caregivers successfully used the prefilled syringe and interacted with the associated labeling, packaging, and instructional materials across 2 human factors studies (a total of 30 patients and 15 caregivers of patients with CIDP or gMG). All participants were able to follow the IFU, prepare, and administer the dose into the simulated injection pad unaided.²

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).²

Findings were based on performance, observed behaviors, subjective feedback, and human factors analyses, and therefore were not traditionally statistically analyzed.²

Frequently Asked Questions

What studies have been conducted for the VYVGART Hytrulo prefilled syringe?

CIDP=chronic inflammatory demyelinating polyneuropathy; gMG=generalized myasthenia gravis; IFU=instructions for use.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infections

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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Q: How do you store/handle the prefilled syringe?

Refrigerate VYVGART Hytrulo prefilled syringes 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 it from the refrigerator or until the expiration date on the carton (whichever occurs first). Record the date removed from the refrigerator on the carton. The prefilled syringe should always be kept in the refrigerator when not in use.¹

Q: What is the volume of the VYVGART Hytrulo prefilled syringe?

VYVGART Hytrulo is available as a 5 mL, single-dose subcutaneous injection containing 200 mg/mL of efgartigimod alfa and 2,000 U/mL of hyaluronidase per prefilled syringe.¹

Q: Why is the volume between the vial and the prefilled syringe different?

To allow for injection with commercially available prefilled syringes (5 mL), argenx reformulated VYVGART Hytrulo.

Each 5.6 mL, single-dose vial of VYVGART Hytrulo contains 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase. Each mL of vial solution contains 180 mg of efgartigimod and 2,000 units of hyaluronidase.¹

Each 5 mL, single-dose prefilled syringe of VYVGART Hytrulo contains 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase. Each mL of prefilled syringe solution contains 200 mg of efgartigimod alfa and 2,000 units of hyaluronidase.¹

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 HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART HYTRULO are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment with VYVGART HYTRULO.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.

Frequently Asked Questions

How do you store/handle the prefilled syringe?

What is the volume of the VYVGART Hytrulo prefilled syringe?

Why is the volume between the vial and the prefilled syringe different?

How long does the injection take with the prefilled syringe? Where should it be administered and who is able to administer?

How should the prefilled syringe injection be prepared?

What are the missed dose instructions for the prefilled syringe?

What additional materials need to be purchased along with the VYVGART Hytrulo prefilled syringe? Will patients need to purchase their own needles?

How can my office clinicians receive training?

How will patients be trained to self-administer? Who is responsible for training the patients?

How can I ensure that my patient is adherent to therapy? What support is provided around compliance?

When can I switch my patient from the vial to the prefilled syringe?

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Q: How long does the injection take with the prefilled syringe? Where should it be administered and who is able to administer?

The VYVGART Hytrulo prefilled syringe takes approximately 20-30 seconds to inject. Before injecting, take the VYVGART Hytrulo prefilled syringe out of the refrigerator for at least 30 minutes to allow it to reach room temperature. Do not use external heat sources.¹ A subcutaneous injection with the prefilled syringe is:

- Injected subcutaneously in the abdomen, at least 2 to 3 inches away from the navel¹
 - Do not inject on areas where the skin is irritated, red, bruised, infected, tender, hard, or into areas where there are moles or scars¹
 - Rotate injection sites for subsequent administrations¹
- Administered by patients or caregivers¹
 - Patients and/or caregivers will receive in-person injection training until ready to inject¹

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

Frequently Asked Questions

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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. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.



Q: How should the prefilled syringe injection be prepared?

- Take the VYVGART Hytrulo prefilled syringe out of the refrigerator at least 30 minutes before injecting to allow it to reach room temperature. Do not use external heat sources³
- Visually inspect that the prefilled syringe solution is yellowish, clear to opalescent. If visible particles are observed, the prefilled syringe must not be used³
- Use aseptic technique when preparing for, and while administering the prefilled syringe. Do not shake the prefilled syringe³
- To administer the prefilled syringe, use a safety needle (25G, 5/8 inches)³
- Connect the syringe to the needle³

Please refer to the [Prescribing Information](#) for the full preparation and administration instructions.

Q: What are the missed dose instructions for the prefilled syringe?

If a scheduled injection is missed, VYVGART Hytrulo may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule.¹

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IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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 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 see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.



Q: What additional materials need to be purchased along with the VYVGART Hytrulo prefilled syringe? Will patients need to purchase their own needles?

Supplies will be provided by specialty pharmacies. These supplies include³:

- Alcohol swabs
- Sharps disposal container
- 25G, 5/8" length, thin wall safety needle
- Sterile gauze and/or adhesive bandage as needed after administration

Q: How can my office clinicians receive training?

For more information about training for your clinicians, fill out a brief form to contact an argenx representative at vyvgarthcp.com.

Q: How will patients be trained to self-administer? Who is responsible for training the patients?

Patients and/or caregivers will receive in-person injection training until ready to inject. argenx has engaged with a network of specialty pharmacies to deliver a robust suite of services to support the patient journey and ensure seamless coordination of care.

- Patients and/or caregivers will receive in-person training until they are comfortable injecting on their own¹
- Training includes education on self-administration, storage, handling, and disposal of the prefilled syringe

Additionally, every patient enrolled in My VYVGART® Path will be connected to a Nurse Case Manager (NCM). NCMs can provide dosing and administration education and ongoing support.

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.

Frequently Asked Questions

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How can I ensure that my patient is adherent to therapy? What support is provided around compliance?

When can I switch my patient from the vial to the prefilled syringe?



Q: How can I ensure that my patient is adherent to therapy? What support is provided around compliance?

The My VYVGART® Path program provides ongoing patient support with regular adherence calls, check-ins, and reminders for patients to follow up with their HCPs.

A Nurse Case Manager (NCM) will be able to provide support for at-home administration options. If a patient does not respond to check-ins from their NCM, the NCM will contact the physician to inquire about their treatment status.

Specialty pharmacies affiliated with argenx undertake a range of responsibilities, such as proper instruction on subcutaneous injection technique and monitoring patients for hypersensitivity reactions for at least 30 minutes.

For more information, please refer to [Your Patient's Self-Injection Treatment Journey](#).

Q: When can I switch my patient from the vial to the prefilled syringe?

Once you submit a prescription for VYVGART Hytrulo prefilled syringe and your patient completes the prior authorization process, they can switch at their next scheduled injection. Patients will receive in-person injection training until ready to self-inject, as determined by an HCP.¹

HCP=healthcare professional.

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion/Injection-Related Reactions (cont'd)

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.

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When can I switch my patient from the vial to the prefilled syringe?



Q: How do I enroll my patient in My VYVGART® Path so they can get started on the prefilled syringe?

There are 2 ways to enroll your patients and get them started with the VYVGART Hytrulo prefilled syringe. Fill out and submit the My VYVGART Path enrollment form online at MyPathEnroll.com or download the enrollment form at vyvgarthcp.com and fax the completed form to 1-833-698-7284. If patients are switching from VYVGART Hytrulo vials to the VYVGART Hytrulo prefilled syringe, they will still need to fill out a new enrollment form.

The VYVGART Hytrulo prefilled syringe was recently approved by the FDA. While payer policies are still being developed, please enroll your patient in My VYVGART Path, argenx's patient support program, to initiate a benefits verification and determine your patient's specific coverage. If needed, your argenx Field Reimbursement Manager (FRM) can provide education on the formulary exception process.

Q: What additional product support does argenx offer to patients?

Patients, caregivers, and healthcare providers can benefit from enrollment in My VYVGART Path, the patient support program that offers:

- Patient-specific benefit verifications, including confirming out-of-pocket costs and prior authorization (PA) requirements
- Screening for commercial co-pay and other potential financial assistance for eligible patients
- Referrals to local and national resources and organizations
- Assistance with your patients' denial and appeal process

Additionally, Field Reimbursement Managers (FRMs) are available to educate your practice about payer policy criteria, navigating the PA and appeals process, and co-pay assistance. Contact your argenx FRM for assistance for your patients.

Contact My VYVGART Path at [1-833-697-2841](tel:1-833-697-2841) for assistance for your patients.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Patients with gMG: 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 in patients with gMG, 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](#) for VYVGART Hytrulo.

Frequently Asked Questions

How do I enroll my patient in My VYVGART® Path so they can get started on the prefilled syringe?

What additional product support does argenx offer to patients?

Is the VYVGART Hytrulo prefilled syringe covered under the Medicare Part B medical benefit or Part D?

How will argenx distribute the VYVGART Hytrulo prefilled syringe? What are the specialty pharmacies that argenx has partnered with?

How will the VYVGART Hytrulo prefilled syringe be supplied?



Q: Is the VYVGART Hytrulo prefilled syringe covered under the Medicare Part B medical benefit or Part D?

The VYVGART Hytrulo prefilled syringe will typically be covered under Medicare Part D. You or your office can contact My VYVGART® Path ([1-833-697-2841](tel:1-833-697-2841)) to:

- Connect with a case coordinator who can assist in finding coverage options for VYVGART Hytrulo
- Insurance benefit verifications, including confirming out-of-pocket costs and prior authorization requirements
- Support for denials and appeals processes for your patient's health plan

Frequently Asked Questions

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IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.



Q: How will argenx distribute the VYVGART Hytrulo prefilled syringe? What are the specialty pharmacies that argenx has partnered with?

- The VYVGART Hytrulo prefilled syringe will be distributed by 9 specialty pharmacies, including:
 1. Accredo Specialty Pharmacy
 2. Option Care Health
 3. Soleo Health
 4. CVS Specialty Pharmacy
 5. Acaria Health Pharmacy
 6. Optum
 7. AllianceRx Walgreens Pharmacy
 8. CenterWell Specialty Pharmacy
 9. Alivia Specialty Pharmacy (for Puerto Rico only)
- My VYVGART Path Nurse Case Managers can ensure the prescription is routed to an in-network specialty pharmacy
- Contact My VYVGART Path at [1-833-697-2841](tel:1-833-697-2841) for assistance for your patients

Frequently Asked Questions

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

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Q: How will the VYVGART Hytrulo prefilled syringe be supplied?

The single-dose prefilled syringe contains 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL (200 mg/2,000 units per mL).

It is available in cartons of 1 or 4 single-dose prefilled syringes:

- NDC 73475-1221-1 for a carton of 1 prefilled syringe
- NDC 73475-1221-4 for a carton of 4 prefilled syringes

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NDC=National Drug Code.

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. 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.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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

VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

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

Infections

VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 in patients with gMG 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

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART HYTRULO are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment 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. 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 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/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

Patients with gMG: 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 in patients with gMG, 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.

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

Please see additional Important Safety Information throughout and full [Prescribing Information](#) for VYVGART Hytrulo.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)

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. Risk and benefits should be considered prior to administering live 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).

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.

For US audiences only.

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