

# HOW TO ACQUIRE VYVGART

Injection for Intravenous Use 400 mg/20 mL vial

VYVGART is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. To acquire VYVGART, please contact the following specialty distributors or specialty pharmacies.

Specialty Distributors	P: PHONE F: FAX	EMAIL	WEBSITE
McKesson Plasma and Biologics	P: 877-625-2566 F: 888-752-7626	mpborders@mckesson.com	connect.mckesson.com
McKesson Specialty Health (for multi-specialty customers)	P: 855-477-9800 F: 800-800-5673	mshcustomercare-mspl @mckesson.com	mscs.mckesson.com
McKesson Specialty Health (for oncology customers)	P: 800-482-6700 F: 855-824-9489	oncologycustomersupport @mckesson.com	mscs.mckesson.com
CuraScript SD	P: 877-599-7748 F: 800-862-6208	customer.service@curascript.com	<u>curascriptsd.com</u>
Cardinal Health Specialty Pharmaceutical Distribution	P: 866-476-1340 F: 614-553-6301	gmb-spd-csorderentry @cardinalhealth.com	orderexpress.cardinalhealth.com or specialtyonline.cardinalhealth.com
ASD Healthcare	P: 800-746-6273 F: 800-547-9413	service@asdhealthcare.com	asdhealthcare.com
Oncology Supply	P: 800-633-7555 F: 800-248-8205	service@oncologysupply.com	oncologysupply.com
Besse Medical	P: 800-543-2111 F: 800-543-8695	service@besse.com	besse.com
BioCareSD	P: 800-304-3064 F: 602-850-6215	order@biocaresd.com	<u>biocaresd.com</u>

Specialty Pharmacies	P: PHONE F: FAX	EMAIL	WEBSITE
Accredo Specialty Pharmacy	P: 888-200-2811 F: 877-773-9233	N/A	accredo.com
Option Care Health	P: 833-812-0669 F: 855-211-5843	oc-argenxreferral@optioncare.com	optioncarehealth.com
Soleo Health	P: 844-503-0912 F: 844-506-6185	mgtherapy@soleohealth.com	soleohealth.com
CVS Specialty	P: 800-237-2767 F: 800-323-2445	N/A	cvsspecialty.com
AcariaHealth Pharmacy	P: 800-511-5144 F: 877-541-1503	N/A	acariahealth.envolvehealth.com
Optum	P: 855-427-4682 F: 877-342-4596	N/A	specialty.optumrx.com
AllianceRx Walgreens Pharmacy	P: 855-244-2555 F: 800-874-9179	N/A	walgreens.com
CenterWell Specialty Pharmacy	P: 800-486-2668 F: 877-405-7940	N/A	centerwellspecialtypharmacy.com

Code Type	Code	Description
NDC <sup>1</sup>	73475-3041-5	400 mg of efgartigimod alfa-fcab in 20 mL (20 mg/mL)
HCPCS code <sup>2</sup>	J9332	Injection, efgartigimod alfa-fcab, 2 mg

## **INDICATION**

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

## **IMPORTANT SAFETY INFORMATION** (see additional ISI on bottom of page 2)

## CONTRAINDICATIONS

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

## Please see full **Prescribing Information**.

## WARNINGS AND PRECAUTIONS

### Infection

VYVGART may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% for VYVGART vs 5% for placebo) and respiratory tract infections (33% for VYVGART vs 29% for placebo). Patients on VYVGART 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 administration in patients with an active infection

References: 1. VYVGART. Prescribing information. argenx US Inc; 2023. 2. Centers for Medicare & Medicaid Services (CMS). July 2022 alpha-numeric HCPCS file. Accessed May 3, 2022. https://www.cms.gov/files/document/2022-hcpcs-application-summary-quarter-1-2022-drugs-and-biologicals.pdf



## **Additional Resources**

If you have additional questions about **VYVGART**, please contact **My VYVGART Path** at **1-833-MY-PATH-1** (**1-833-697-2841**) where you can be connected to the appropriate resource.





## **Storage and Handling Requirements**

VYVGART (efgartigimod alfa-fcab) injection is a preservative free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied as 400 mg/20 mL (20 mg/mL) in one single-dose vial per carton (NDC 73475-3041-5).

Store VYVGART vials refrigerated at  $2^{\circ}$ C to  $8^{\circ}$ C ( $36^{\circ}$ F to  $46^{\circ}$ F) in the original carton to protect from light until time of use. **DO NOT FREEZE. DO NOT SHAKE.** 

## **Infusion Site Locator**

Click <u>here</u> to find infusion centers in your area. These centers specialize in infusion treatments and have an experienced staff to help you through the infusion process.

## You can access downloadable resources online by clicking here and scrolling to the bottom of the web page.

## **IMPORTANT SAFETY INFORMATION** (cont.)

## Infection (cont.)

until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART until the infection has resolved.

#### **Immunization**

Immunization with vaccines during VYVGART treatment has not been studied; the safety with live or liveattenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART.

## **Hypersensitivity Reactions**

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. 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 VYVGART. 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 patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. 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 premedications.

#### **ADVERSE REACTIONS**

In Study 1, the most common (≥10%) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

#### **USE IN SPECIFIC POPULATIONS**

### Pregnancy

As VYVGART 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 in utero.

#### Lactation

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

## Please see the <u>full Prescribing Information</u>.

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

