

Indication

VYVGART® is indicated for the treatment of adult patients with gMG (generalized myasthenia gravis) who are AChR-Ab+ (anti-acetylcholine receptor antibody positive).

Pharmacological Classification

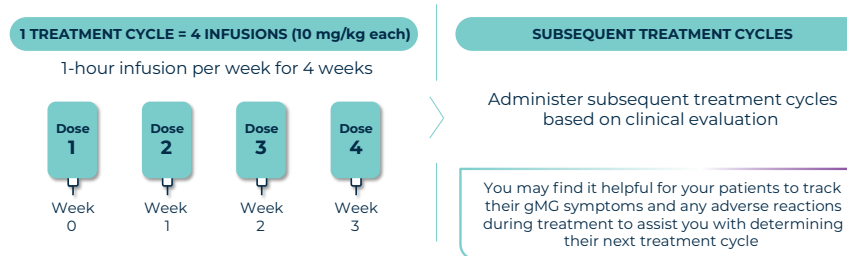
Neonatal Fc-Receptor (FcRn) Antagonist

Mechanism of Action (MoA)

VYVGART® is a human IgG1 antibody fragment that binds to FcRn and inhibits its interaction with IgG. This results in increased degradation of IgG and reduction of circulating IgG and pathological IgG autoantibodies.

Dosing

The recommended dose of VYVGART® is **10 mg/kg**, given in treatment cycles of **once-weekly 1-hour IV infusions for 4 weeks**



The safety of initiating a subsequent treatment cycle sooner than 4 weeks from the last infusion of the previous treatment cycle has not been established

Administration

VYVGART® should be administered via IV (intravenous infusion) by a healthcare professional.

The recommended dose of VYVGART® is 10mg/kg administered as an intravenous infusion over 1 hour, once weekly for 4 weeks. VYVGART® must be diluted with 0.9% Sodium Chloride Injection, USP prior to administration.

Visually inspect VYVGART® diluted solution for particles or discoloration prior to administration. Do not use if discolored, or if opaque or foreign particles are seen.

Infuse the total 125 mL of diluted solution intravenously over 1 hour via a 0.2 micron in-line filter. VYVGART® is to be given immediately after dilution and complete the infusion within 4 hours of dilution. If immediate use is not possible, the diluted solution may be stored, refrigerated at 2°C to 8°C (36°F to 46°F), for up to 8 hours.

In patients weighing 120 kg or more, the recommended dose of VYVGART® is 1200 mg (3 vials) per infusion.

Other medications should not be injected into infusion side ports or mixed with VYVGART®

After administration of VYVGART® flush the entire line with 0.9% Sodium Chloride Injection, USP.

Monitor patients during administration, and for 1 hour thereafter, for clinical signs and symptoms of infusion reactions. Should a reaction occur, discontinue the infusion, and institute appropriate supportive measures, if needed. Once resolved, and based on the severity of the reaction, administration may be cautiously resumed, if needed at a slower rate based on clinical evaluation.

Please refer to section 7 warnings and precautions of product monograph.

Storage and Stability

VYVGART® injection is a preservative-free, sterile, colourless to slightly yellow, clear to slightly opalescent solution supplied as 400mg/20mL (20 mg/mL) in one single-dose vial.

Store VYVGART® vials refrigerated between 2°C and 8°C in the original carton.

Protect from light until time of use.

Do not freeze. Do not shake. Do not warm by any means other than ambient air.

Clinical Use

Not indicated for use in patients <18 years of age.

Although there were no age-related differences observed in patients aged >65 years in the study, the number of patients aged 65 and over is not sufficient to determine whether they would respond similarly to younger patients.

Contraindications

VYVGART® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient or component of the container.

For a complete listing, please see dosage forms, strengths, composition and packaging.

Warnings And Precautions

There are no available data on the use for **VYVGART®** during pregnancy.

Immune

Infections:

The most common infections observed in clinical trials were upper respiratory tract infections. The majority of infections were mild to moderate in severity.

Immunization:

Immunization with vaccines during **VYVGART®** treatment has not been studied.

Sensitivity/Resistance

Infusion-related reactions:

Hypersensitivity reactions such as rash, pruritis or anaphylactic reactions may occur. In clinical trials, infusion-related reactions were mild or moderate and did not lead to treatment discontinuation. Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of infusion reactions.

Adverse Reaction Overview

In the placebo-controlled Phase 3 Study 1704, the most common adverse reactions ($\geq 10\%$) seen in patients who received at least one dose of **VYVGART®** included headache (29% vs 28% placebo), upper respiratory tract infection (11% vs 5% placebo), and urinary tract infection (10% vs 5% placebo).

The MyPATH Patient Support Program

The MyPATH Patient Support Program (PSP), is committed to making every patient treatment journey with **VYVGART®** a little easier, every step of the way.

Understand VYVGART® treatment

Navigate access to VYVGART®

Coordinate all aspects of receiving
VYVGART® treatment

To learn more about VYVGART®, please contact your argenx representative or medical information at medinfoca@argenx.com
For more information on the MyPATH PSP, call 1-877-697-2840 or email info@mypathpsp.ca

VYVGART®
efgartigimod alfa
400 mg/20 mL


MyPATH
VYVGART® Patient Support Program