

**PATIENT INFORMATION**  
**VYVGART HYTRULO®** [viv' gart hye troo' loe]  
(efgartigimod alfa and hyaluronidase-qvfc)  
injection, for subcutaneous use

**What is VYVGART HYTRULO?**

VYVGART HYTRULO is a prescription medicine used to treat adults with:

- generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- chronic inflammatory demyelinating polyneuropathy (CIDP).

It is not known if VYVGART HYTRULO is safe and effective in children.

**Do not take VYVGART HYTRULO** if you:

- are allergic to efgartigimod alfa, hyaluronidase, or any of the ingredients in VYVGART HYTRULO. See the end of this leaflet for a complete list of ingredients in VYVGART HYTRULO. VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

**Before taking VYVGART HYTRULO, tell your healthcare provider about all of your medical conditions, including if you:**

- have an infection or fever.
- have recently received or are scheduled to receive any vaccinations.
- have any history of allergic reactions.
- have kidney (renal) problems.
- are pregnant or plan to become pregnant. It is not known whether VYVGART HYTRULO will harm your unborn baby.
  - **Pregnancy Exposure Registry.** There is a pregnancy exposure registry for women who use VYVGART HYTRULO during pregnancy. The purpose of this registry is to collect information about your health and your baby. Your healthcare provider can enroll you in this registry. You may also enroll yourself or get more information about the registry by calling 1-855-272-6524 or going to <https://www.Vyvgartpregnancy.com>
- are breastfeeding or plan to breastfeed. It is not known if VYVGART HYTRULO passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I take VYVGART HYTRULO?**

- Take VYVGART HYTRULO exactly as your healthcare provider tells you to take it.
- VYVGART HYTRULO is injected under your skin (subcutaneously) only. **Do not** inject into a vein (intravenously).
- For gMG, VYVGART HYTRULO is injected 1 time weekly for 4 weeks (treatment cycle). Your healthcare provider will tell you when to administer your future treatment cycles.
- For CIDP, VYVGART HYTRULO is injected 1 time weekly.
- VYVGART HYTRULO comes in a single-dose prefilled syringe and single-dose vial.
- Only a healthcare provider should inject VYVGART HYTRULO using the single-dose vial.
- If you are prescribed the VYVGART HYTRULO prefilled syringe, you or your caregiver should receive training on the right way to prepare and inject VYVGART HYTRULO prefilled syringe.
- **Do not** try to inject VYVGART HYTRULO prefilled syringe until you have been shown the right way by a healthcare provider. **See the detailed Instructions for Use that comes with VYVGART HYTRULO prefilled syringe.**
- Monitor for signs and symptoms of an allergic reaction for at least 30 minutes after administration. See

### “What are the possible side effects of VYVGART HYTRULO?”

- If you miss a dose of VYVGART HYTRULO, you may give the injection for up to 3 days after the missed dose. After that, continue with the normal time between doses (dosing schedule).

### What are the possible side effects of VYVGART HYTRULO?

#### VYVGART HYTRULO can cause side effects which can be serious, including:

- **Infection.** VYVGART HYTRULO may increase the risk of infection. If you have an active infection, your healthcare provider should delay your treatment with VYVGART HYTRULO until your infection is gone. Tell your healthcare provider right away if you get any of the following signs and symptoms of an infection:
  - fever
  - chills
  - frequent and painful urination
  - cough
  - pain and blockage of nasal passages
  - wheezing
  - shortness of breath
  - sore throat
  - excess phlegm
  - nasal discharge
- **Allergic reactions (hypersensitivity reactions).** VYVGART HYTRULO can cause allergic reactions that can be severe. These reactions can happen during, shortly after, or weeks after your VYVGART HYTRULO injection. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction:
  - rash
  - swelling of the face, lips, throat, or tongue
  - shortness of breath
  - hives
  - trouble breathing
  - low blood pressure
  - fainting
- **Infusion or injection-related reactions.** VYVGART HYTRULO can cause infusion or injection-related reactions. These reactions can happen during or shortly after your VYVGART HYTRULO injection. Tell your healthcare provider if you have any of the following symptoms of an infusion or injection-related reaction:
  - high blood pressure
  - chills
  - shivering
  - chest, stomach, or back pain

#### The most common side effects of VYVGART HYTRULO include:

- respiratory tract infection
- injection site reactions
- headache
- urinary tract infection

These are not all the possible side effects of VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### How should I store VYVGART HYTRULO?

#### Refrigerated

- Store VYVGART HYTRULO in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Only warm VYVGART HYTRULO by letting it sit on a flat surface for at least 30 minutes for the prefilled syringe and 15 minutes for the vial. Do not warm VYVGART HYTRULO any other way (e.g., with an external heat source).
- Store VYVGART HYTRULO in the original carton to protect from light until you are ready to use it.

- Do not freeze VYVGART HYTRULO.
- Do not shake VYVGART HYTRULO.
- Do not use VYVGART HYTRULO past the expiration date.
- VYVGART HYTRULO is for one-time use only (single-dose).
- Remove from the refrigerator only the dose you are preparing to inject. Future doses should remain refrigerated until ready to use.

#### Room temperature

- If needed, VYVGART HYTRULO may be stored at room temperature. Record the date you removed VYVGART HYTRULO from the refrigerator.
  - Single-dose prefilled syringe may be stored at room temperature (up to 86°F (30°C)) for up to 30 days. When removed from the refrigerator and brought to room temperature VYVGART HYTRULO must be used within 30 days or thrown away.
  - Single-dose vial may be stored at room temperature (between 68°F to 77°F (20°C to 25°C)) for up to 3 days. When removed from the refrigerator and brought to room temperature, VYVGART HYTRULO must be used within 3 days or thrown away.
- **Do not put VYVGART HYTRULO back into the refrigerator after it has warmed to room temperature.**

**Keep VYVGART HYTRULO and all medicines out of the reach of children.**

#### **General information about the safe and effective use of VYVGART HYTRULO.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VYVGART HYTRULO for a condition for which it was not prescribed. Do not give VYVGART HYTRULO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VYVGART HYTRULO that is written for health professionals.

#### **What are the ingredients in VYVGART HYTRULO?**

**Active ingredients:** efgartigimod alfa and hyaluronidase (human recombinant)

**Inactive ingredients:**

- single-dose prefilled syringe: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, sodium chloride, sucrose, and water for injection, USP
- single-dose vial: histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 20, sodium chloride, sucrose and water for injection, USP

Manufactured by:

- argenx BV Industriepark 7, 9052 Zwijnaarde, Belgium, U.S. License No. 2217
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