PATIENT INFORMATION
IMAAVY® (im-AH-vee)
(nipocalimab-aahu)
injection, for intravenous use

What is IMAAVY?

IMAAVY is a prescription medicine used to treat adults and children 12 years of age and older with:

- generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
- warm Autoimmune Hemolytic Anemia (wAIHA) currently or previously treated with corticosteroids.

It is not known if IMAAVY is safe and effective in children under 12 years of age.

Do not receive IMAAVY if you

have a history of a severe allergic reactions to nipocalimab-aahu or any of the ingredients in IMAAVY. See the end of this Patient Information leaflet for a complete list of ingredients in IMAAVY.

Before receiving IMAAVY, tell your healthcare provider about all of your medical conditions, including if you:

- have had an allergic reaction to IMAAVY. Ask your healthcare provider if you are not sure.
- have or had any recent infections or have any symptoms of infection.
- have or had shingles (herpes zoster) or mono (mononucleosis caused by Epstein-Barr virus).
- have recently received or are scheduled to receive an immunization (vaccine). You should not receive live vaccines during treatment with IMAAVY.
- are pregnant or plan to become pregnant. It is not known if IMAAVY will harm your unborn baby.
    - **Pregnancy Safety Study.** There is a pregnancy safety study for IMAAVY. If IMAAVY is given during pregnancy or you become pregnant while receiving IMAAVY, your healthcare provider should report IMAAVY exposure by contacting Janssen at 1-800-526-7736 or www.IMAAVY.com.
- are breastfeeding or plan to breastfeed. IMAAVY can pass into your breast milk. It is not known if IMAAVY will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with IMAAVY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. IMAAVY may affect the way that some medicines work.

How will I receive IMAAVY?

- Your healthcare provider will give you IMAAVY through a needle placed into your vein (intravenous [IV] infusion).
- **For gMG,** you will receive a starting dose of IMAAVY infusion lasting at least 30 minutes. Two weeks later you will receive your next dose of IMAAVY infusion lasting at least 15 minutes. You will receive your following doses every 2 weeks.
- **For wAIHA,** you will receive a starting dose of IMAAVY infusion lasting at least 30 minutes. Four weeks later you will receive your next dose of IMAAVY infusion lasting at least 15 minutes. You will receive your following doses every 4 weeks.
- Your healthcare provider should monitor you for reactions to IMAAVY during the infusion and for 30 minutes after each infusion. If you have a reaction during your IMAAVY infusion, your healthcare provider may infuse IMAAVY more slowly, or give you medicine before your infusion, or stop your infusion if your reaction is severe.
- If you miss a scheduled IMAAVY infusion, you should receive your next dose as soon as possible.

What should I avoid while receiving IMAAVY?

- You should not receive live vaccines during treatment with IMAAVY.

What are the possible side effects of IMAAVY?

IMAAVY can cause serious side effects, including:

- **Infections.** IMAAVY may increase your risk of infections, including serious infections. If you have an infection, your healthcare provider will treat your infection or delay your infusion until your infection is gone. Tell your healthcare provider right away if you get any of the following symptoms of infection:
  - fever
  - chills
  - shivering
  - cough
  - sore throat
  - fever blisters
  - burning when you urinate
  - trouble breathing
- **Allergic (hypersensitivity) reactions.** Allergic reactions can happen during or up to a few weeks after your IMAAVY infusion. Tell your healthcare provider and get emergency medical help right away if you get any of these symptoms during or after your IMAAVY infusion:
  - swelling of your face, lips, mouth, tongue, or throat
  - trouble swallowing or breathing
  - hives
  - itchy rash
  - chest pain or tightness
- **Infusion-related reactions.** Tell your healthcare provider right away if you get any of the following symptoms during or within a few days after your infusion of IMAAVY:
  - headache
  - rash
  - nausea
  - fatigue
  - dizziness
  - chills
  - flu-like symptoms
  - redness of skin

The most common side effects in people with gMG treated with IMAAVY include:

- infection in parts of your body that you use for breathing (respiratory tract infection)
- swelling in your hands, ankles, or feet (peripheral edema)
- muscle spasms

The most common side effects in people with wAIHA treated with IMAAVY include:

- swelling in your hands, ankles, or feet (peripheral edema)
- diarrhea
- fever (pyrexia)

These are not all of the possible side effects of IMAAVY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IMAAVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about IMAAVY that is written for health professionals.

What are the ingredients in IMAAVY?

Active ingredient: nipocalimab-aahu

Inactive ingredients: arginine hydrochloride, histidine, L-histidine monohydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injection.

Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA
U.S. License Number 1864
For patent information: www.janssenpatents.com
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For more information, call 1-800-526-7736 or go to www.IMAAVY.com

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: 08/2026