

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**IMAAVY**[®]

Nipocalimab for injection

This Patient Medication Information is written for the person who will be taking **IMAAVY**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **IMAAVY**, talk to a healthcare professional.

What is IMAAVY used for:

IMAAVY is a prescription medicine called a monoclonal antibody and contains the active substance nipocalimab. IMAAVY is used together with standard therapy to treat adults and children (12 years and older) with a disease called generalized Myasthenia Gravis (gMG). Eligible patients are antibody positive for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK).

Generalized MG causes weakness of muscles, including those involved in movement and/or breathing. This is an “autoimmune disorder” which means that it is caused by your antibodies. These antibodies target and destroy proteins that are responsible for communication between nerves and muscles. This then results in muscle weakness.

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

How does IMAAVY work:

IMAAVY belongs to a group of medicines called monoclonal antibodies. This medicine works by blocking a protein in the body called neonatal Fc receptor (FcRn). By blocking FcRn, IMAAVY decreases the level of IgG autoantibodies (antibodies against your own body) that attack parts of a person’s own body by mistake in generalised Myasthenia Gravis.

The ingredients in IMAAVY are:

Medicinal ingredients: nipocalimab

Non-medicinal ingredients: The inactive ingredients include L-Arginine hydrochloride, L-Histidine, L-Histidine monohydrochloride monohydrate, L-Methionine, Polysorbate 80, Sucrose, Water for Injections.

IMAAVY comes in the following dosage forms:

- 300 mg/1.62 mL (185 mg/mL) solution, for intravenous use
- 1200 mg/6.5 mL (185 mg/mL) solution, for intravenous use

Do not use IMAAVY if:

- you are allergic to nipocalimab or any of the other ingredients in IMAAVY.

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you take IMAAVY. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to IMAAVY. Ask your healthcare provider if you are not sure.
- are being treated for an infection or have any symptoms of infection, for example fever, chills, shivering, cough, sore throat, fever blisters, or burning when you urinate.
- had a herpes zoster infection (shingles), because IMAAVY may allow it to come back. Tell your healthcare professional if you get a painful skin rash with blisters as these can be signs of shingles.
- have an ongoing infection. Before starting or during treatment with this medicine, inform your healthcare professional if you have any infections.
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY should not receive live vaccines.
- taking medicines including prescription and over-the-counter medicine, vitamins, and herbal supplements.

Other warnings you should know about:

- **Children:** Do not give this medicine to children below 12 years of age because the safety and efficacy of IMAAVY have not been established in this population.
- **Pregnancy:** Tell your healthcare professional or nurse before you are given IMAAVY if you are pregnant, think you might be pregnant or are planning to have a baby.
- **Breast-feeding:** Talk to your healthcare professional if you are breast-feeding or are planning to breast-feed. You and your healthcare professional should discuss to decide if breast-feeding while using IMAAVY is appropriate.
- If you have higher than normal blood fat (cholesterol) levels before starting IMAAVY, your healthcare professional may monitor your cholesterol levels.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IMAAVY:

- medicines that bind to the human neonatal Fc receptor (FcRn) (e.g., immunoglobulin products, monoclonal antibodies, or antibody derivatives containing the human Fc domain of the IgG subclass)

When concomitant long-term use of medications that bind to the FcRn is essential for patient care, the healthcare professional will closely monitor for reduced effectiveness and consider discontinuing IMAAVY, or using alternative therapies.

How to take IMAAVY:

- IMAAVY will be given to you by your healthcare provider by infusion into your vein (IV).
- You will receive a starting dose of IV IMAAVY infusion usually over 30 minutes, and then you will receive an additional infusion every two weeks usually over 15 minutes. If you have a reaction during your IMAAVY infusion, your healthcare provider may decide to give IMAAVY more slowly or to stop your infusion.

Usual dose:

The dose you receive will depend on your bodyweight and will be administered as an infusion every 2 weeks. Your healthcare professional will determine when further infusions are needed.

- The first dose is 30 mg/kg over approximately 30 minutes by intravenous injection. This will be given by your healthcare professional.
- Every 2 weeks after the first dose, you will be given 15 mg/kg over approximately 15 minutes.

Overdose:

This medicine will be given by your healthcare professional. In the unlikely event that you are given too much (an overdose), your healthcare professional will check you for side effects.

If you think you, or a person you are caring for, have taken too much IMAAVY contact a healthcare professional, hospital emergency department or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or no symptoms.

Missed dose:

It is very important to go to all your appointments to make sure your treatment works. If you miss an appointment, make another one as soon as possible.

Possible side effects from using IMAAVY:

These are not all the possible side effects you may feel when taking IMAAVY. If you experience any side effects not listed here, contact your healthcare professional.

- Infusion-related reactions including rash, redness of the skin (erythema), discomfort and infusion site pain
- Stomach pain
- Diarrhea
- Nausea
- Swollen hands, ankles or feet
- Fever
- Urinary tract infection
- Muscle spasms
- Feeling dizzy
- Difficulty sleeping
- Shingles
- Chest and lung infection (respiratory tract infection)

Serious side effects and what to do about them

Frequency/Side Effect/Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Allergic reactions: a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, itchy rash (hives) and chest pain or tightness.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store in a refrigerator at 2°C to 8°C in the original carton.
Do not freeze. Do not shake. Protect from light until time of use.
Do not use IMAAVY beyond the expiration date (EXP) on the carton.
Keep out of the sight and reach of children.

If you want more information about IMAAVY:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website: ([Drug Product Database: Access the database](https://drugproductdatabase.ca)); the manufacturer's website (innovativemedicine.jnj.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

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