

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **UPLIZNA**[®]

Inebilizumab for injection

This Patient Medication Information is written for the person who will be taking **UPLIZNA**. 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 **UPLIZNA**, talk to a healthcare professional.

What **UPLIZNA** is used for:

- **UPLIZNA** is used to treat adults with neuromyelitis optica spectrum disorders (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive.
- **UPLIZNA** is used to treat adults with Immunoglobulin G4-related disease (IgG4-RD) to reduce the frequency of flares. IgG4-RD is a rare condition which can affect multiple organs and tissues in the body.
- It is not known if **UPLIZNA** is safe or effective in children.

How **UPLIZNA** works:

Inebilizumab is a monoclonal antibody (a type of protein) that attaches to immune cells called B cells and destroys them. In most people with NMOSD, B cells produce antibodies that attack AQP4, a protein involved in nerve cell function. By reducing the numbers of B cells, the medicine is expected to prevent damage to nerve cells and reduce the symptoms of the condition.

In people with IgG4-RD, the immune system damages the body's own tissues. Patients with IgG4-RD may have high levels of a specific type of antibody called IgG4. B cells producing IgG4 build up in affected tissues and contribute to organ damage. **UPLIZNA** reduces the number of B cells in IgG4-RD patients.

The ingredients in **UPLIZNA** are:

Medicinal ingredient(s): inebilizumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sodium chloride, trehalose dihydrate, and water for injection

UPLIZNA comes in the following dosage form(s):

Injection: 3 vials of 100 mg/10 mL (10 mg/mL)

Do not use **UPLIZNA** if:

- you are hypersensitive to the drug or to any of the ingredients within the drug.
- you have had a life-threatening infusion reaction to **UPLIZNA**.
- you have a severe active infection or a chronic active infection such as hepatitis B virus infection.
- you have active or untreated inactive (latent) tuberculosis.

- you have a history of progressive multifocal leukoencephalopathy (PML).
- you are in a severely immunocompromised state.
- you have active malignancy.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take UPLIZNA. Talk about any health conditions or problems you may have, including if you:

- have or think you have an infection.
- are severely immunocompromised, including HIV infection.
- have ever taken, currently take, or plan to take medicines that affect your immune system, or other treatments for NMOSD. These medicines may increase your risk of getting an infection.
- have or have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have or have ever had hepatitis C.
- have or have ever had tuberculosis.
- have had progressing multifocal leukoencephalopathy (PML).
- have active malignancy.
- have had a recent vaccination or are scheduled to receive any vaccinations. You should receive any required vaccines at least 4 weeks before you start treatment with UPLIZNA.
- have a baby and you were exposed to UPLIZNA during pregnancy. It is important to tell your baby's healthcare professional, so they can decide when your baby should receive any vaccinations.
- are pregnant or plan to become pregnant. It is not known if UPLIZNA will harm your unborn baby. Females should use effective birth control (contraception) during treatment with UPLIZNA and for 6 months after your last infusion of UPLIZNA.
- are breastfeeding or plan to breastfeed. It is not known if UPLIZNA passes into your breast milk. Talk to your healthcare professional about the best way to feed your baby if you receive UPLIZNA.

Other warnings you should know about:

Allergic Reactions:

UPLIZNA can cause infusion reactions, including anaphylaxis. Tell your healthcare professional immediately if you get any of these symptoms during your UPLIZNA infusion:

Headache, nausea, drowsiness, shortness of breath, fever, aches, palpitation or other signs or symptoms.

Decreased Immunoglobulins

UPLIZNA may cause a decrease in immunoglobulins (proteins in your blood that help your immune system fight infection). Your healthcare professional will do blood tests to check your blood immunoglobulin 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 UPLIZNA:

No relevant drug-drug interactions are known however, use of UPLIZNA with drugs that suppress your immune system may increase the risk of infection. Inform healthcare professional of any other medications you are taking.

How to take UPLIZNA:

- UPLIZNA will be given to you by a qualified healthcare professional.
- UPLIZNA is given through a needle placed in a vein (IV or intravenous infusion) in your arm.
- Before treatment with UPLIZNA, your healthcare professional will complete specific screening tests and will give you a corticosteroid medicine, an antihistamine, and a fever prevention medicine to help infusion reactions become less frequent or less severe.

Usual dose:

- Each dose of UPLIZNA consists of 300 mg of the drug.
- Your first dose of UPLIZNA will be given as 2 separate infusions, 2 weeks apart.
- Your next doses of UPLIZNA will be given as one infusion every 6 months.
- Each infusion will last about 1 hour and 30 minutes. After each infusion, you will be monitored by a healthcare professional for at least 1 hour.

Overdose:

UPLIZNA is given by a healthcare professional only. This minimizes the chance of an overdose.

If you think you, or a person you are caring for, have taken too much UPLIZNA 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 symptoms.

Missed dose:

If you miss an appointment for an infusion, contact your healthcare professional to make another one right away.

Possible side effects from using UPLIZNA:

These are not all the possible side effects you may have when taking UPLIZNA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Urinary tract infection
- Common cold
- Joint pain
- Upper respiratory tract infection
- Headache
- Back pain

- Infusion related reaction
- Fever
- Muscle pain
- Lung infection (pneumonia)

Serious side effects and what to do about them:

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Infections: painful and frequent urination, nasal congestion, runny nose, sore throat, fever, chills, cough, body aches.		X	
Uncommon			
Infusion reactions: headache, sleepiness, fever, rash, nausea, shortness of breath, muscle aches, palpitations.		X	
Rare			
Hepatitis B virus (HBV) reactivation: fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay-coloured stool, joint pain, jaundice		X	
Progressive Multifocal Leukoencephalopathy (PML): weakness on one side of the body, changes in vision, confusion, loss of coordination arms and legs, changes in thinking or memory, changes in personality.		X	

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

Storage:

Store UPLIZNA in a refrigerator at 2°C to 8°C in original carton.

Protect from light. Do not freeze. Do not shake.

Store vials upright.

Keep out of reach and sight of children.

If you want more information about UPLIZNA:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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