EMADOC-1829012207-45350
EMEA/H/C/005818

Uplizna (*inebilizumab*)

An overview of Uplizna and why it is authorised in the EU

What is Uplizna and what is it used for?

Uplizna is a medicine used to treat adults with:

- neuromyelitis optica spectrum disorders (NMOSD), inflammatory disorders that affect mainly the optic nerve (which connects the eye to the brain) and the spinal cord. This leads to impaired vision, loss of sensation, loss of bladder control, weakness and paralysis of the arms and legs. The medicine is used in patients with antibodies against a protein called aquaporin-4 (AQP4);
- immunoglobulin G4 (IgG4)-related disease. IgG4-related disease is an autoimmune condition (a disease caused by the body's own defence system attacking normal tissue) that can cause fibrosis (tissue scarring) and inflammation in one or multiple organs. It is used in people whose disease is active (causing symptoms and tissue damage);
- generalized myasthenia gravis (gMG), a disease that leads to muscle weakness and tiredness; it is used in people whose immune system produces antibodies against proteins called acetylcholine receptor or muscle-specific tyrosine kinase, which are found on muscle cells. It is given together with other medicines used for the treatment of myasthenia gravis.

Uplizna contains the active substance inebilizumab.

How is Uplizna used?

Treatment with Uplizna should be given under the supervision of a doctor experienced in treating NMOSD, active IgG4-related disease or gMG, and who has access to medical support in case of serious reactions to the treatment. The medicine can only be obtained with a prescription.

Uplizna is available as a solution for infusion (drip) into a vein. Treatment starts with two infusions given two weeks apart and continues with one infusion every six months after that. Before treatment, patients should take corticosteroids and medicines to reduce fever. They should also be monitored during and one hour after the treatment for serious side effects related to the infusion. Vaccinations should be up to date and any infection should be well controlled before starting treatment with Uplizna.

For more information about using Uplizna, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

© European Medicines Agency, 2026. Reproduction is authorised provided the source is acknowledged.

How does Uplizna work?

Inebilizumab is a monoclonal antibody (a type of protein) that attaches to immune cells called B cells and destroys them. B cells play an important role in the development of NMOSD, IgG4-related disease and gMG. In most people with NMOSD, B cells produce antibodies that attack AQP4, a protein involved in nerve cell function. In people with IgG4-related disease, B cells are involved in causing the fibrosis and inflammation. By reducing the numbers of B cells, the medicine is expected to reduce the symptoms of the condition being treated.

What benefits of Uplizna have been shown in studies?

Uplizna was shown to be effective at reducing the risk of flare-ups of NMOSD or IgG4-related disease symptoms.

One main study, involving 230 adults with NMOSD, showed that of the patients with AQP4 antibodies, 18 out of 161 (11%) patients given Uplizna experienced a flare-up of symptoms over the course of 197 days compared with 22 out of 52 (42%) patients given placebo (a dummy treatment).

A second main study involved 135 adults with active IgG4-related disease. The study results showed that, during the course of 52 weeks, 7 out of 68 (10%) patients given Uplizna experienced a flare-up of symptoms compared with 40 out of 67 (60%) of those given placebo.

A third main study showed that Uplizna was effective in the treatment of adults with myasthenia gravis. The study involved 238 adults with moderate to severe myasthenia gravis who had antibodies against acetylcholine receptor or muscle-specific tyrosine kinase and who received either Uplizna or placebo. The study looked at the effect of treatment using a myasthenia gravis specific activities of daily living (MG-ADL) scale, which measures the impact of the disease on patients' daily activities. The scale ranges from 0 to 24 and higher scores indicate more severe symptoms.

After 26 weeks, people treated with Uplizna had a reduction of around 4.3 points in their MG-ADL scores, compared with a reduction of around 3 points for patients on placebo.

What are the risks associated with Uplizna?

For the full list of side effects and restrictions with Uplizna, see the package leaflet.

The most common side effects with Uplizna (which may affect more than 1 in 10 people) include urinary tract infections (infections of the structures that carry urine), inflammation and infections of the nose and throat, joint pain, back pain, lymphopenia (low levels of lymphocytes, a type of white blood cell) and headache.

Some side effects can be serious. The most frequent (which may affect more than 1 in 10 people) include infections.

Uplizna must not be used in patients with ongoing infections, including hepatitis B and tuberculosis, or who have had progressive multifocal leukoencephalopathy (a rare brain infection) in the past. It must also not be used by people with severely weakened immune systems or active cancers.

Why is Uplizna authorised in the EU?

Uplizna is effective at reducing NMOSD flare-ups in adults. The European Medicines Agency considered this to be a clinically important outcome in people with NMOSD as symptom flare-ups can cause serious, permanent disability. Uplizna has also been found to be effective at reducing the risk of flare-ups in people with active IgG4-related disease

Uplizna was also shown to be effective at reducing the symptoms of myasthenia gravis, as measured by a reduction in the MG-ADL scores. Although this effect was modest, the results were considered robust and clinically relevant.

These conditions are rare and the medicine was therefore investigated in small numbers of participants; however, the safety of the medicine was considered manageable. The Agency therefore decided that Uplizna's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Uplizna?

The company that markets Uplizna should provide a patient card to inform patients about the risk of infection with Uplizna, how to recognise symptoms of infections, including those of progressive multifocal leukoencephalopathy, and to seek medical attention if these arise.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Uplizna have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Uplizna are continuously monitored. Side effects reported with Uplizna are carefully evaluated and any necessary action taken to protect patients.

Other information about Uplizna

Uplizna received a marketing authorisation valid throughout the EU on 25 April 2022.

Further information on Uplizna can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/uplizna.

This overview was last updated in 03-2026.