EMA/192406/2022
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).

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 with 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 the 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 reactions 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.

How does Uplizna work?

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.

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

What benefits of Uplizna have been shown in studies?

Uplizna was shown to be effective at increasing the length of time between flare-ups of NMOSD symptoms.

The 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).

What are the risks associated with Uplizna?

The most common side effects with Uplizna (which may affect more than 1 in 10 people) are urinary tract infections (infections of the structures that carry urine), inflammation and infections of the nose and throat, joint pain and back pain.

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

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

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. NMOSD is a rare disease and the medicine was therefore tested in a small number 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 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

Uplinza 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 04-2022.