

PATIENT CARD

Important Risk Minimization Information for Patients

UPLIZNA[®]▼
(inebilizumab)

▼ Healthcare professionals are asked to report each case of a suspected adverse reaction. For information on reporting adverse reactions, see last page.

For further information, please refer to the patient information leaflet, or contact Medical Information by e-mail at: medinfo-mea@amgen.com

Important information for Healthcare professionals: _____

Patient's Name:

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This patient is receiving treatment for Neuromyelitis Optica Spectrum Disorder (NMOSD) with Uplizna.

UPLIZNA CAN LEAD TO SERIOUS ADVERSE REACTIONS.

Pay attention to signs and symptoms to detect infections early:

- Severe infection
- Reactivation of viruses
- Opportunistic infection
- Progressive multifocal leukoencephalopathy (PML)

UPLIZNA is a medication for adults to treat anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorders (NMOSD). In NMOSD, the immune system attacks healthy parts of the central nervous system (CNS). These episodes cause an inflammation of the CNS. The affected parts of the CNS are generally the optic nerve, spinal cord, brain and brain stem. UPLIZNA is an antibody targeting B cells which attack your CNS. By depleting the B cells, the inflammation and likelihood of episodes is reduced.

Among the symptoms of an NMOSD episode are:

- Changes in your vision
- Weakness of the extremities
- Muscle cramps or other pain
- Difficulty in controlling bladder and bowel
- Severe nausea, vomiting or hiccups

The CNS may be damaged through repeated flare-ups (also called “episodes”). These episodes may cause severe and permanent disabilities including paralysis or blindness. NMOSD may even impair breathing.

IMPORTANT INFORMATION FOR PATIENTS: POSSIBLE ADVERSE REACTIONS TO UPLIZNA

The risk for infection is increased.

Severe or unusual infections may occur.

Tell your physician if you experience symptoms of an infection such as:

- Stuffy or runny nose
- Sore throat or cough
- Red, painful or blisters on the skin
- Painful and frequent urination
- Shortness of breath
- Burning sensation, numbness or tingling sensation
- Sleepiness
- Body aches
- Fever or chills
- Stabbing pain

Virus infections you had in the past may be reactivated.

This may happen if the immune system is weakened. One example for a serious infection is hepatitis, a liver infection. Before each treatment, a hepatitis test will be performed. Tell your physician right away about any symptoms of infection.

Vaccination Information

Inform your healthcare provider if you have recently received a vaccination or are scheduled to receive one. Any required vaccinations should be completed at least 4 weeks before starting treatment with Uplizna.

Progressive Multifocal Leukoencephalopathy (PML) is a rare infection of the brain. It may start with mild symptoms. However, it may get worse over days or weeks.

Symptoms of PML are:

- Weakness on one side of the body
- Changes in vision
- Confusion
- Heavy arms and legs
- Changes in thinking, memory or personality
- Newly occurring seizures

**Seek immediate medical attention,
if you have one of these symptoms.**

Carry this card with you at all times.

You can help by reporting any side effects you may get to:

Amgen Local QPPV in Saudi Arabia

Abdulkareem Bin Mubarak,

Tel: +966112799300

E-mail: Safety-MEA@amgen.com

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA)

SFDA call center:19999

E-mail: npc.drug@sfda.gov.sa Online: <http://ade.sfda.gov.sa/>



For any medical inquiries, please reach out to: medinfo-mea@amgen.com

Contact your physician if you experience symptoms of infection or PML:

Name
Phone number
Medical Center