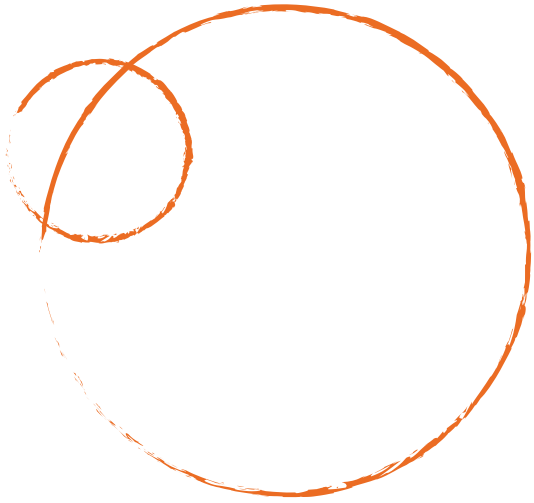
Fact Sheet

Ravulizumab | Ultomiris ®

NMOSD FDA-Approved Drug



Revised 6/12/2024 | This information sheet has been reviewed and approved by members of SRNA's Medical and Scientific Council. Access our NMOSD Therapeutics at a Glance Tool at srna.ngo/nmosd-ther to compare all NMOSD drugs.

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How does it work?

Ravulizumab is a complement inhibitor; the complement system is a part of the immune system that aids your body in attacking foreign microbes and promoting inflammation. It is similar to eculizumab or SOLIRIS but has been modified to last longer than eculizumab.

When should I not take this drug?

Do not receive ravulizumab if you have a meningococcal infection or have not been vaccinated against meningitis infection unless your doctor decides that urgent treatment with ravulizumab is needed.

How do I take it?

Intravenous (IV) infusion in an outpatient infusion center, doctor's office, or at home.

How often do I take it?

One infusion every 8 weeks; to start therapy, there are two infusions 2 weeks apart, followed by infusions every 8 weeks.

What is the typical dosage?

The recommended intravenous ravulizumab loading and maintenance dosing in adults weighing 40 kg (~88 lbs.) or greater, is based on body weight.

How much does it reduce my risk of relapse?

In the CHAMPION-NMOSD clinical trial, ravulizumab reduced the risk of relapse by roughly 98.6%.

What are the side effects?

The most common side effects include headache, upper respiratory tract infections, high blood pressure, nausea, vomiting, and diarrhea. Infusion reactions may occur, ranging from flu-like symptoms, low blood pressure, hives to swelling, shortness of breath and, in more severe cases, shock. A serious infection called meningococcal meningitis may occur; this is from a bacterial infection that can cause inflammation around the brain.

What should I do to prepare?

Receive a meningococcal vaccine at least two weeks before starting this medication; speak with your doctors about which vaccine is best for you.

What ongoing monitoring should occur?

NMOSD patients receiving ravulizumab should be monitored for early signs of meningococcal infection. No ongoing monitoring is recommended following discontinuation of ravulizumab.

Who makes this medication?

Ravulizumab is produced by Alexion – AstraZeneca Rare Disease.

How can I get help paying for it?

Alexion – AstraZeneca Rare Disease offers patient support through their OneSource program.

Can I take it if I'm pregnant?

There is no FDA pregnancy category assigned to ravulizumab. Ravulizumab has been used safely for the treatment of other medical conditions during pregnancy on an individual basis, but has not been studied in large groups of pregnant people. It is unclear if this medication is generally safe for use in pregnancy and should be discussed with your doctor.

Clinical Trial Information

In the CHAMPION-NMOSD clinical trial, 58 AQP-4 antibody positive individuals received ravulizumab. They were compared to the placebo group in the PREVENT trial, which was the clinical trial that studied eculizumab. Both groups were allowed to continue other immunosuppressive medications (steroids, azathioprine, mycophenolate modafinil, etc.).

Will my insurance cover it?

This will depend on your insurance company and the billing code your doctor uses. For specific questions, call the customer service phone number on the back of your insurance card with the name of the drug in question, as well as ICD (diagnostic) code your doctor uses.

Is it FDA approved for NMOSD?

Yes, for aquaporin-4 (AQP4) positive NMOSD (also known as seropositive NMOSD).