

aHUS STORIES: PATRICK STARTS ON ULTOMIRIS

TO PROTECT THE PRIVACY OF PATIENTS, PHOTOS ARE FOR ILLUSTRATION ONLY.



ULTOMIRIS[®]
(ravulizumab-cwvz)
injection for intravenous use
300 mg/3 mL vial

INDICATION

What is ULTOMIRIS?

ULTOMIRIS is a prescription medicine used to treat:

- adults and children 1 month of age and older with a disease called atypical Hemolytic Uremic Syndrome (aHUS). ULTOMIRIS is not used in treating people with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
- adults with aHUS when administered subcutaneously (under your skin).

It is not known if ULTOMIRIS is safe and effective in children younger than 1 month of age. Subcutaneous administration of ULTOMIRIS has not been evaluated and is not approved for use in children.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ULTOMIRIS?

ULTOMIRIS is a medicine that affects your immune system and can lower the ability of your immune system to fight infections.

- ULTOMIRIS increases your chance of getting serious and life-threatening meningococcal infections that may quickly become life-threatening and cause death if not recognized and treated early.

1. You must receive meningococcal vaccines at least 2 weeks before your first dose of ULTOMIRIS if you are not vaccinated.
2. If your healthcare provider decided that urgent treatment with ULTOMIRIS is needed, you should receive meningococcal vaccination as soon as possible.
3. If you have not been vaccinated and ULTOMIRIS therapy must be initiated immediately, you should also receive 2 weeks of antibiotics with your vaccinations.
4. If you had a meningococcal vaccine in the past, you might need additional vaccination. Your healthcare provider will decide if you need additional vaccination.
5. Meningococcal vaccines reduce but do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection: headache with nausea or vomiting, headache and fever, headache with a stiff neck or stiff back, fever, fever and a rash, confusion, muscle aches with flu-like symptoms and eyes sensitive to light.

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information and Medication Guide for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening meningococcal infections/sepsis.

Remember to speak with your doctor about your symptoms and how to manage atypical-HUS.

This is Patrick. He is 4 years old and was just diagnosed with atypical-HUS.

aHUS Stories: PATRICK starts on ULTOMIRIS



Based on an actual patient

Patrick

Age: 4 years old
Height: 3 ft 5 in
Weight: 38.6 lbs
Diagnosed with atypical-HUS

Likes playing with dinosaurs
and his favorite color is red

“WHEN PATRICK WAS DIAGNOSED, I KNEW LIFE
WOULD NEVER BE THE SAME. I ALSO KNEW
WE DIDN'T HAVE TO FACE THIS ALONE.”

— Patrick's mother



How did your doctor describe atypical-HUS?

- Our doctor told us that atypical-HUS is a rare, life-threatening disorder that can be caused by either triggers such as medication or genetics.^{1,2}
- It occurs when the body can no longer control the complement system, which is a part of the immune system that normally kills bacteria and destroys other harmful foreign substances in the blood.^{2,3}
- When someone like Patrick has atypical-HUS, uncontrolled activity of the complement system can damage blood vessels. Platelets, which are cells found in blood, can also become overactive.^{4,5}
- Overactive platelets can lead to TMA (also known as thrombotic microangiopathy), a condition that causes clots in small blood vessels. TMA ultimately leads to the destruction of blood cells and blocks blood flow to vital organs, leading to sudden organ failure or loss of organ function over time.^{4,6}

How did you first learn Patrick had atypical-HUS?

- We brought him to the hospital when he was vomiting and experiencing seizures. At the hospital, it was found that he had potential areas of the brain not receiving oxygen that were detected by MRI (magnetic resonance imaging), which were initially treated with medication. It was also confirmed he had only one kidney. Laboratory tests were performed and showed evidence of thrombotic microangiopathy (TMA).⁷
- By excluding similar related disorders, our doctor was confident diagnosing Patrick with atypical-HUS.^{4,8}

What types of tests did your doctor perform on Patrick?

To get an atypical-HUS diagnosis, other causes of TMA have to be ruled out.^{1,8}

Our doctor performed several different laboratory tests to help diagnose atypical-HUS. These included looking at:

- **Platelet count: Low** platelet levels in the blood are common in patients with atypical-HUS.
- **Lactate dehydrogenase (LDH) levels: High** LDH levels are common in patients with atypical-HUS and are caused by LDH being released into the blood by damaged cells, like ruptured blood cells.
- **Measures of kidney function: High** creatinine or **low** estimated glomerular filtration rate (eGFR) are indicators of poor kidney function, which is often observed in patients with atypical-HUS.

Other tests were also performed that helped solidify diagnosis.

What were the results?

- Our doctor told us there was no definitive test to determine if Patrick has atypical-HUS. TMA is also commonly seen in patients with shiga toxin-producing *E coli* (STEC-HUS) or thrombotic thrombocytopenic purpura (TTP).^{4,8}
- To diagnose atypical-HUS, our doctor first had to exclude the possibility of these other disorders.^{4,8}
- After reviewing the laboratory test results, our doctor excluded STEC-HUS and TTP and confirmed that Patrick had atypical-HUS.^{4,8}

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He is 4 years old, and he gets his ULTOMIRIS every 4 weeks.

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“ULTOMIRIS GAVE US A PATH FORWARD.
THE FREEDOM PROVIDED BY THE 4-WEEK DOSING
SCHEDULE ALLOWS US TO FIT HIS INFUSIONS INTO
OUR LIVES, NOT THE OTHER WAY AROUND.”

— Patrick’s father

SELECT IMPORTANT SAFETY INFORMATION

Your healthcare provider will give you a Patient Safety Card about the risk of meningococcal infection.

Carry it with you at all times during treatment and for 8 months after your last ULTOMIRIS dose. It is important to show this card to any healthcare provider or nurse to help them diagnose and treat you quickly.

ULTOMIRIS is only available through a program called the ULTOMIRIS REMS.

Before you can receive ULTOMIRIS, your healthcare provider must: enroll in the ULTOMIRIS REMS program; counsel you about the risk of meningococcal infection; give you information and a **Patient Safety Card** about

What were your next steps?

- Twelve hours after our doctor confirmed Patrick had atypical-HUS, Patrick received his starting dose of ULTOMIRIS. Two weeks later he received his second dose of ULTOMIRIS.^{7,9}
 - Two weeks after the starting dose, ULTOMIRIS is infused every 4 or 8 weeks for pediatric patients (depending on body weight). For this reason, Patrick continued to receive ULTOMIRIS treatment every 4 weeks following the second dose.^{7,9}
 - After each infusion, patients should be monitored for at least 1 hour for infusion reactions. Please see **Page 4** for more information about infusion-related reactions.⁹
- When our doctor first decided that urgent treatment with ULTOMIRIS was needed, she made sure Patrick received meningococcal vaccinations. Because ULTOMIRIS was started immediately, Patrick also received two weeks of antibiotics to further reduce the risk of infection. We were also given a **Patient Safety Card** about the risk of meningococcal infection.^{7,9}

What is ULTOMIRIS?

- ULTOMIRIS is the first and only FDA-approved long-acting prescription medication for treating atypical-HUS.⁹
- It works by binding and blocking the C5 complement protein to prevent TMA or blood clots. In atypical-HUS, TMA is what ultimately causes vital organs to either suddenly fail or lose their ability to function over time.⁹

ULTOMIRIS controls C5 immediately^{8,9}

- 100% (14/14) of pediatric patients on ULTOMIRIS had complete C5 control after their first infusion.

the symptoms and your risk of meningococcal infection (as discussed above); and make sure that you are vaccinated with a meningococcal vaccine, and if needed, get revaccinated with the meningococcal vaccine. Ask your healthcare provider if you are not sure if you need to be revaccinated.

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With ULTOMIRIS, C5 control is sustained for up to 8 weeks⁹

- This means that C5 control lasts the full 8 weeks between infusions for adult patients. Depending on body weight, pediatric patients receive infusions every 4 or 8 weeks in order to experience the same sustained C5 control.

What went into your decision to choose ULTOMIRIS?

- Atypical-HUS is a serious and lethal disease when untreated. Our doctor told us the immediate need was to inhibit complement activity to stop the damage caused to the blood vessels.^{4,7}
 - Our doctor discussed ULTOMIRIS as a long-acting treatment option for Patrick and reviewed important information, including⁹:
 - How the medication works
 - Benefits and safety profile, including side effects
 - Risks for serious infections with ULTOMIRIS and the requirement for getting vaccinated against meningococcal infections
 - Weight-based dosing schedule
 - The most common side effects of ULTOMIRIS in people with atypical-HUS are upper respiratory infection, diarrhea, nausea, vomiting, headache, high blood pressure and fever.
- Ultimately, we felt that ULTOMIRIS was the option for us⁸**
- We were happy that ULTOMIRIS has a dose and schedule that both works with Patrick’s weight now and can be changed as he grows older.

How did you cope with this life change?

- Patrick having a serious disease like atypical-HUS was unexpected.
- The resources and the community we found along the way—whether talking to our doctors, working with our OneSource Case Manager, or talking to other patients—showed us we were not alone on our journey.

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OneSource™ is a complimentary, personalized support program offered by Alexion. OneSource is staffed by Alexion Case Managers, all of whom have extensive knowledge of atypical-HUS and can assist you every step of the way. They are ready to provide the support and resources you need—whatever your care plan may be.



Disease Information

Contact OneSource for an atypical-HUS Starter Kit.



Health Insurance Navigation

Receive information to understand your insurance plan and your coverage options for the Alexion therapy.



Community Connections

Join webinars where you can listen to a doctor speak about atypical-HUS management, hear a patient or caregiver share their story about living with atypical-HUS, ask questions, and gather information to potentially discuss with your doctor.



Ongoing Support

Get personalized support for maintaining therapy during major life events, such as a change in job, insurance status, provider, or location.



INTERESTED IN TELLING YOUR STORY? BECOME A STAR AMBASSADOR!

To learn more about the atypical-HUS STAR Ambassador Program, CALL 1-844-378-2127 OR EMAIL MYSTORY@STARSAMBASSADOR.COM.

ONESOURCE IS HERE TO HELP

Enroll in OneSource for resources and support. CALL 1-888-765-4747 OR ENROLL ONLINE AT ALEXIONONESOURCE.COM.

**DON'T NAVIGATE YOUR JOURNEY WITH ATYPICAL-HUS ALONE.
GET YOUR FREE PATIENT RESOURCE KIT TODAY AT
WWW.aHUSJOURNEY.COM.**

SELECT IMPORTANT SAFETY INFORMATION

ULTOMIRIS may also increase the risk of other types of serious infections. Make sure your child receives vaccinations against *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib) if treated with ULTOMIRIS. Call your healthcare provider right away if you have any new signs or symptoms of infection.

Who should not receive ULTOMIRIS?

Do not receive ULTOMIRIS if you have a meningococcal infection or have not been vaccinated against meningococcal infection unless your healthcare provider decides that urgent treatment with ULTOMIRIS is needed.

Before you receive ULTOMIRIS, tell your healthcare provider about all of your medical conditions, including if you: have an infection or fever, are pregnant or plan to become pregnant, and are breastfeeding or plan to breastfeed. It is not known if ULTOMIRIS will harm your unborn baby or if it passes into your breast milk. You should not breastfeed during treatment and for 8 months after your final dose of ULTOMIRIS.

Tell your healthcare provider about all the vaccines you receive and medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements which could affect your treatment.

If you have aHUS, your healthcare provider will need to monitor you closely for at least 12 months after stopping treatment for signs of worsening aHUS or problems related to a type of abnormal clotting and breakdown of your red blood cells called thrombotic microangiopathy (TMA). Symptoms or problems that can happen with TMA may include: confusion or loss of consciousness, seizures, chest pain (angina), difficulty breathing and blood clots or stroke.

ULTOMIRIS can cause serious side effects including allergic reactions to acrylic adhesive. Allergic reactions to the acrylic adhesive may happen with your subcutaneous ULTOMIRIS treatment. If you have an allergic reaction during the delivery of subcutaneous ULTOMIRIS, remove the on-body injector and get medical help right away. Your healthcare provider may treat you with medicines to help prevent or treat allergic reaction symptoms as needed.

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SELECT IMPORTANT SAFETY INFORMATION

What are the possible side effects of ULTOMIRIS?

ULTOMIRIS can cause serious side effects including infusion-related reactions. Symptoms of an infusion-related reaction with ULTOMIRIS may include lower back pain, tiredness, feeling faint, discomfort in your arms or legs, bad taste, or drowsiness. Stop treatment of ULTOMIRIS and tell your healthcare provider or nurse right away if you develop these symptoms, or any other symptoms during your ULTOMIRIS infusion that may mean you are having a serious infusion reaction, including: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, and feel faint or pass out.

The most common side effects of ULTOMIRIS in people treated for aHUS are upper respiratory tract infection, diarrhea, nausea, vomiting, headache, high blood pressure and fever.

The most common side effects of subcutaneous administration of ULTOMIRIS in adults treated for PNH and aHUS are local injection site reactions.

References

1. Asif A, et al. *J Nephrol.* 2017;30:347-362. **2.** Noris M, et al. *Nat Rev Nephrol.* 2012;8:622-633. **3.** Zhang K, et al. *Hematol Rep.* 2017;9(2):7053. **4.** Azoulay E, et al. *Chest.* 2017;152:424-434. **5.** National Heart, Lung, and Blood Institute. Accessed January 20, 2021. <https://www.nhlbi.nih.gov/health-topics/thrombocytopenia> **6.** Jokiranta TS. *Blood.* 2017;129(21):2847-2856. **7.** Data on file [ALXN1210-aHUS-312 CSR]. **8.** Laurence J. *Clin Adv Hematol Oncol.* 2016;14:2-15. **9.** ULTOMIRIS. Prescribing information. Alexion Pharmaceuticals, Inc.; 2020.

Tell your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of ULTOMIRIS. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider right away if you miss an ULTOMIRIS infusion or for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Read the Instructions for Use that comes with subcutaneous ULTOMIRIS for instructions about the right way to prepare and give your subcutaneous ULTOMIRIS injections through an on-body injector.

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