

ULTOMIRIS REMS (Risk Evaluation and Mitigation Strategy)

What is ULTOMIRIS REMS ?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product

The purpose of the ULTOMIRIS REMS is to mitigate the occurrence and morbidity associated with meningococcal infections by informing healthcare providers and patients about the:

- Increased risk of meningococcal infections with ULTOMIRIS
- Early signs of invasive meningococcal infections, and
- Need for immediate medical evaluation of signs and symptoms consistent with possible meningococcal infections.

PROGRAM REQUIREMENTS

ULTOMIRIS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

HCPs who prescribe ULTOMIRIS must be specifically certified. Certification consists of review of REMS educational materials and enrollment in the ULTOMIRIS REMS program.

HEALTHCARE PROVIDER CERTIFICATION

Certification in the ULTOMIRIS REMS includes the following steps:

STEP
01

Review the ULTOMIRIS REMS HCP Educational Materials

-  [Prescribing Information](#)
-  [Prescriber Safety Brochure](#)
-  [Patient Safety Brochure](#)
-  [ULTOMIRIS Patient Safety Card](#)

STEP
02

Enroll in the ULTOMIRIS REMS

[Click here to complete the ULTOMIRIS REMS Prescriber Enrollment online](#)

Or

[Print and sign the Prescriber Enrollment Form](#)

- Mail the form to Alexion Pharmaceutical, Inc.
ATTN: REMS Program, 121 Seaport Boulevard, Boston, MA 02210
- Fax the form to ULTOMIRIS REMS at 1-877-580-2596
- Scan and email the form to rems@alexion.com

PATIENT COUNSELING

HCPs should

- Counsel patients using both the Patient Safety Brochure and Patient Safety Card. Provide these materials to your patients.
- Remind patients to carry the Patient Safety Card with them at all times
- Advise their patients that this safety card contains important safety information about the risk of meningococcal infection that they need to be aware of before they are given ULTOMIRIS and during their treatment with ULTOMIRIS
- Remind their patients to show this card to any doctor involved in their treatment
- Explain to their patients that if they cannot reach their doctor, they should go to the emergency room immediately and show the emergency room staff the ULTOMIRIS Patient Safety Card. Even if a patient stops using ULTOMIRIS, they should keep their ULTOMIRIS Patient Safety Card with them.

To order a ULTOMIRIS Patient Safety Card, contact ULTOMIRIS REMS at 1-888-765-4747

The Spanish versions of the Patient education material can be downloaded from below:

-  [Spanish ULTOMIRIS Patient Safety Card](#)
-  [Spanish Patient Safety Brochure](#)

REPORTING ADVERSE EVENTS

HCPs should report all suspected adverse events, including reports of meningococcal infection by contacting Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or reporting the information to the FDA MedWatch Reporting System by phone at 1.800.FDA.1088 (1.800.332.1088) or by mail using Form 3500 at <http://www.fda.gov/MedWatch>



**DOWNLOAD THE
PATIENT SAFETY CARD**



**DOWNLOAD PATIENT
SAFETY BROCHURE**



ULTOMIRIS REMS

Contact us

 **Phone**
1-888-765-4747

 **FAX**
1-877-580-2596 (ALXN)

 **Hours of Operation**
Monday – Friday
8:30 am – 5:00 pm
Eastern Time

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ROSANNA W SETSE
04/30/2020 01:57:47 PM