



SOLIRIS REMS (Risk Evaluation and Mitigation Strategy)

What is the Soliris 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 SOLIRIS 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 Soliris
- Early signs of invasive meningococcal infections, and
- Need for immediate medical evaluation of signs and symptoms consistent with possible meningococcal infections.

[Download the Patient Safety Card](#)

[Download Patient Safety Brochure](#)

Program Requirements

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

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

Soliris REMS

Contact us



Phone:

1.888.SOLIRIS (1.888.765.4747)

FAX: 1.877.580.2596 (ALXN)

Hours of Operation:

Monday – Friday

8:30 am – 5:00 pm

Eastern Time

Healthcare Provider Certification

Certification in the SOLIRIS REMS includes the following steps:

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Review the SOLIRIS REMS HCP Educational Materials:

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

Enroll in the SOLIRIS REMS Program:

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

OR

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

- Mail the form to Soliris REMS, Alexion Pharmaceuticals, 121 Seaport

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Boulevard, Boston, MA 02210.

- Fax the form to Soliris REMS at 1-877-580-2596 (ALXN); or
- Scan and email the form to rems@alexion.com

Patient Counselling

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 Soliris and during their treatment with Soliris.
- 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 Soliris Patient Safety Card. Even if a patient stops using Soliris, they should keep their Soliris Patient Safety Card with them.



To order a Soliris Patient Safety Card, contact Soliris REMS at 1.888.SOLIRIS (1.888.765.4747).

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

- 📄 [Spanish Soliris 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 1.888.Soliris (1.888.765.4747); 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>