



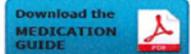
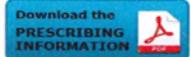
SOLIRIS REMS (Risk Evaluation and Mitigation Strategy)

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.



SOLIRIS REMS OneSource Safety Support Program

Contact us

Phone:
1.888.SOLIRIS (1.888.765.4747)
Fax: 1.877.580.2596 (ALXN)

Hours of Operation:
Monday - Friday
8:00am - 5:00pm
Eastern Time

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 program.

Healthcare Provider Certification

Certification in the SOLIRIS REMS OneSource Safety Support Program includes the following steps:

- 1** Review the SOLIRIS REMS HCP Educational Materials:

 - [Prescriber Brochure; Important Safety Information about Soliris](#)
 - [Dosing and Administration Guide](#)
 - [Patient Safety Brochure; Important Safety Information about Soliris](#)
 - [Patient Introductory Letter and Voluntary Enrollment Form](#)
 - [Soliris Patient Safety Card](#)
- 2** Enroll in the SOLIRIS REMS Program:

Click here to complete the SOLIRIS REMS Prescriber Enrollment online.

OR

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

 - Mail the form to OneSource Safety Support Program, Alexion Pharmaceuticals, 352 Knotter Drive, Cheshire, CT 06410-9868; or,
 - Fax the form to Soliris OneSource Safety Program at 1-877-580-2596 (ALXN); or
 - Scan and email the form to OSSP@alxn.com

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

- [Spanish Patient Introductory Letter and Voluntary Enrollment Form](#)
- [Spanish Soliris Patient Safety Card](#)
- [Spanish Patient Safety Brochure, Important Safety Information about Soliris](#)

The Soliris Patient Safety Card

HCPs should provide their patients with a Soliris Patient Safety Card to carry with them at all times. This safety card contains important safety information about the risk of meningococcal infection that patients need to be aware of before they are given Soliris and during their treatment with Soliris. Remind them to show this card to any doctor involved in their treatment.



HCPs should 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 for 3 months after the last Soliris dose, since side effects may occur a long time after their last dose of Soliris.

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

Reporting Adverse Events

HCPs should report all suspected adverse event experiences, including reports of meningococcal infection by contacting Alexion Pharmaceuticals, Inc., (OneSource Safety Support Program) 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 www.fda.gov/MedWatch