

Initial REMS Approval: 06/2010
Last modified/revised: 07/2016

BLA 125166/172 SOLIRIS[®] (ECULIZUMAB)

RECOMBINANT HUMANIZED MONOCLONAL ANTIBODY

Alexion Pharmaceuticals, Inc.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S)

The goals of the REMS are:

- To mitigate the occurrence and morbidity associated with meningococcal infections
- To educate Healthcare Professionals (HCPs) and Patients (or Caregivers, or Legal Guardians) regarding:
 - the increased risk of meningococcal infections with Soliris[®] (eculizumab)
 - the early signs of invasive meningococcal infections, and
 - the need for immediate medical evaluation of signs and symptoms consistent with possible meningococcal infections

II. REMS ELEMENTS

A. Medication Guide

Alexion will ensure that a Medication Guide is dispensed with each prescription of Soliris and in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

B. Elements to Assure Safe Use

Healthcare providers who prescribe Soliris are specially certified.

- a. Prescriber certification is based on prescriber agreement that the prescriber will:
 - i) Counsel patients and provide the patient educational materials to the patient, including the Soliris Patient Safety Card and the Medication Guide
 - ii) Provide the Medication Guide to the patient prior to each infusion
 - iii) Review the educational materials (Soliris Patient Safety Card, Prescriber Introductory Letter, Prescriber Safety Brochure *Important Safety Information about Soliris*, Patient Safety Brochure *Important Safety Information about Soliris*, and Dosing and Administration Guide) and the product labeling and comply with the directions for safe use including ensuring patients receive a meningococcal vaccine.
 - iv) Promptly report to Alexion at 1-844-259-6783 or to the FDA at 1-800-332-1088 or 1-800-300-43874 (serious life-threatening) cases of meningococcal infection, including the patients' clinical outcomes
- b. The prescriber will fax the completed enrollment form to 1-877-580-2596 (ALXN), email the completed form to OSSP@alxn.com, or mail the form to Alexion Pharmaceuticals, Inc.; Attn: OneSource Safety Support Program;100 College Street, New Haven, CT 06510. A prescriber may also complete the enrollment by phone with Alexion at 1-888-765-4747 or obtain enrollment documents via the Soliris REMS website at www.solirisrems.com. A prescriber may also complete the enrollment on the internet via the Soliris REMS-dedicated website at www.solirisrems.com.
- c. Alexion will contact certified prescribers every year to provide the educational materials (Medication Guide, Soliris Patient Safety Card, Prescriber Safety Brochure, and *Important Safety Information about Soliris*, Patient Safety Brochure, *Important Safety Information about Soliris*, and Dosing and Administration Guide). The educational materials and enrollment form will also be available on a REMS-dedicated webpage at www.solirisrems.com.

The REMS-dedicated website (www.solirisrems.com) will be accessible directly or from a link from www.soliris.net.

- d. The following materials are part of the REMS and are appended
 - (1) Soliris Patient Safety Card
 - (2) Prescriber Introductory Letter and Enrollment Form
 - (3) Patient Safety Brochure, *Important Safety Information about Soliris*
 - (4) Prescriber Safety Brochure, *Important Safety Information about Soliris*
 - (5) Dosing and Administration Guide
 - (6) Soliris REMS website (www.solirisrems.com)
- e. Alexion will maintain a database of certified prescribers in the REMS program, and will ensure that Soliris is distributed only to certified prescribers. Alexion will ensure that prescribers comply with the requirements of the REMS Program.

C. Timetable for Submission of Assessments

REMS assessments will be submitted to the FDA every two years beginning June 1, 2015. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Alexion will submit each assessment so that it will be received by the FDA on or before the due date.