

# ZILBRYSQ REMS

## HEALTHCARE PROVIDER SAFETY BROCHURE

### ZILBRYSQ<sup>®</sup> (zilucoplan) Injection

For more information about the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy):

Visit: [www.ZILBRYSQREMS.com](http://www.ZILBRYSQREMS.com)

Call: 1-877-414-8353

Monday through Friday, 9:00 am to 5:00 pm ET

This brochure is for healthcare providers who will prescribe or dispense ZILBRYSQ (zilucoplan). It describes:

- The increased risk of meningococcal infections with ZILBRYSQ
- Information about meningococcal vaccinations and antibacterial drug prophylaxis in patients receiving ZILBRYSQ
- How to counsel patients with the **Patient Guide** and **Patient Safety Card**
- How to become certified to prescribe or dispense ZILBRYSQ

Please see Prescribing Information, including BOXED WARNING for serious meningococcal infections, for more detailed safety information about ZILBRYSQ.

## What is ZILBRYSQ?

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ZILBRYSQ is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

### Risk of Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infections may rapidly become life-threatening or fatal if not recognized and treated early.

- At least 2 weeks prior to the first dose of ZILBRYSQ, complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- Revaccinate patients in accordance with ACIP recommendations considering the duration of ZILBRYSQ therapy.
- If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with both MenACWY and MenB vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis.
- Because of inhibition of complement activity by ZILBRYSQ and risk of infection caused by nongroupable strains of *N. meningitidis*, vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
- Inform patients of these signs and symptoms of meningococcal infections and instruct patients to seek immediate medical care if these signs and symptoms occur.
- Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

Please see Prescribing Information, including **BOXED WARNING** for serious meningococcal infections, for more detailed safety information about ZILBRYSQ.

# What Do Prescribers Need to Do to Prescribe ZILBRYSQ?

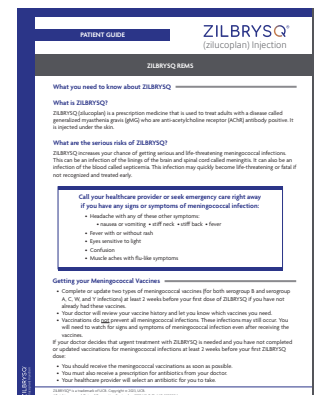
Prescribers must be certified in the ZILBRYSQ REMS before they are eligible to prescribe ZILBRYSQ.

## To become certified to prescribe ZILBRYSQ

- Review the ZILBRYSQ **Prescribing Information**
- Review the **Healthcare Provider Safety Brochure** (this document)
- Review the **Patient Guide**
- Review the **Patient Safety Card**
- Complete and submit the **Prescriber Enrollment Form** to the ZILBRYSQ REMS.

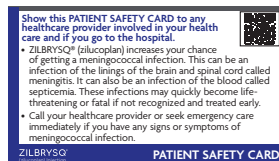
## Before initiating a patient's ZILBRYSQ treatment

- Assess the patient for unresolved meningococcal infection and do not initiate ZILBRYSQ therapy in any patient with this infection.
- Assess the patient's meningococcal vaccination status for serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate the patient as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor, which may be found at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html>. A link to these recommendations may be found at the ZILBRYSQ REMS website, [www.ZILBRYSQREMS.com](http://www.ZILBRYSQREMS.com).
- For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment with ZILBRYSQ and must start ZILBRYSQ urgently:
  - Administer meningococcal vaccines as soon as possible.
  - Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel patients who will receive ZILBRYSQ on the increased risk of meningococcal infections, the importance of vaccination (both MenACWY and MenB), and the need for antibiotics if they are not up to date on both meningococcal vaccines and have to start ZILBRYSQ right away. Provide patients with both the **Patient Guide** and **Patient Safety Card**.
  - The **Patient Guide** provides information your patients can carry with them to find out more about ZILBRYSQ, including:
    - The risk of meningococcal infections
    - The need for meningococcal vaccination
    - Signs and symptoms of meningococcal infections



- The **Patient Safety Card** provides quick, portable guidance for the patient and for any of the patient's healthcare providers about:

- The patient's ZILBRYSQ treatment
  - Signs and symptoms of meningococcal infection
  - Importance of immediate care for any suspected meningococcal infection
- Discuss the importance and the proper use of the safety card with any patient who is receiving ZILBRYSQ.
    - Counsel patients to carry the safety card at all times during therapy and for 2 months after the last dose of ZILBRYSQ.
    - Counsel patients to show the card to any healthcare provider involved in their care.
  - Tell your patients about the risk of meningococcal infections and that this risk may continue for several weeks after the last dose of ZILBRYSQ.
  - Advise patients of the need to complete or update both meningococcal vaccines for serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) according to current medical guidelines.
  - Advise patients that meningococcal vaccines do not prevent all meningococcal infections.
  - Advise patients of the need for antibiotics if they are not up to date on both meningococcal vaccines and have to start ZILBRYSQ right away.
  - Educate patients to recognize the early signs and symptoms of meningococcal infections and instruct patients to seek immediate medical attention if any of these signs or symptoms occur. Signs and symptoms include:
    - Headache with any of the following:
      - Nausea or vomiting
      - Stiff neck or stiff back
      - Fever
    - Fever with or without rash
    - Eyes sensitive to light
    - Confusion
    - Muscle aches with flu-like symptoms



## During ZILBRYSQ treatment

- Assess the patient for early signs and symptoms of meningococcal infections and evaluate immediately, if infection is suspected.
- For patients who are being treated for meningococcal infection: Withhold administration of ZILBRYSQ.
- Revaccinate patients according to the current ACIP recommendations on meningococcal vaccination for patients receiving a complement inhibitor.

## At all times

- Report adverse events suggestive of meningococcal infection in patients taking ZILBRYSQ, including the patient's clinical outcomes, to UCB, Inc. by calling 1-844-599-2273

## What Do Pharmacists Need to Do to Dispense ZILBRYSQ?

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Pharmacies must be certified in the ZILBRYSQ REMS before they are eligible to dispense ZILBRYSQ.

### To become certified to dispense ZILBRYSQ

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Review the **Healthcare Provider Safety Brochure** (this document).
- Submit a completed **Pharmacy Enrollment Form** to the ZILBRYSQ REMS.
- Establish processes to ensure that the pharmacy meets all REMS requirements, including:
  - Providing training for all staff involved in dispensing ZILBRYSQ using the **Healthcare Provider Safety Brochure**.
  - Verifying the prescriber is certified and document the findings.
  - Contacting the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis if needed before treatment initiation and document the findings.
  - For patients who are not up to date with meningococcal vaccines when starting treatment: Contact the prescriber before dispensing prescriptions up to 6 months after the first dose to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis if needed and document the findings.

### Before dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

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## For up to 6 months after dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

## After the first 6 months of dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.

## To maintain certification to dispense

- If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

## At all times

- Do not distribute, transfer, loan, or sell ZILBRYSQ, except to certified pharmacies.
- Report any adverse events suggestive of meningococcal infection in a patient taking ZILBRYSQ to UCB, Inc. by email at [ds.usa@ucb.com](mailto:ds.usa@ucb.com).
- Maintain records of staff's completion of REMS training.
- Maintain records to show that processes and procedures that fulfill all REMS requirements are in place and being followed.
- Comply with audits carried out by UCB, Inc. or a third party acting on behalf of UCB, Inc. to ensure that all processes and procedures are in place and being followed.

## About the ZILBRYSQ REMS

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A REMS is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits associated with a medication outweigh its risks.

- ZILBRYSQ is available only through a restricted distribution program that is part of the ZILBRYSQ REMS.
- The goal of the ZILBRYSQ REMS is to mitigate the risk of serious meningococcal infections.

1. Patients are vaccinated against meningococcal infections caused by *Neisseria meningitidis* serogroups A, C, W, Y (MenACWY) and serogroup B (MenB) prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.

2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

### Adverse Events

Potential cases of meningococcal infections should be reported immediately to UCB, Inc. at 1-844-599-2273.

You are encouraged to report other adverse reactions of ZILBRYSQ to UCB Inc. or the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

This guide does not provide a complete description of the risks associated with ZILBRYSQ.

Please see the Prescribing Information, including the BOXED WARNING regarding serious meningococcal infection, for more detailed safety information on ZILBRYSQ.

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