



# ZILBRYSQ<sup>®</sup>

(zilucoplan) Injection

## Fulfillment Resource Guide

A guide to help your office navigate patient access for ZILBRYSQ (zilucoplan)

### INDICATION

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

### IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

#### WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.
- Patients receiving ZILBRYSQ are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

The information provided in this guide is of a general nature and for informational purposes only. It is intended to assist healthcare professionals in understanding the fulfillment process for ZILBRYSQ when appropriately prescribed or administered. Coverage policies change periodically and often without warning. The responsibility to determine coverage parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this guide in no way represents a statement, promise, or guarantee by UCB, Inc. concerning access for ZILBRYSQ and administration services, and UCB, Inc. does not recommend or endorse the use of any particular diagnosis or procedure code.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).**

## ZILBRYSQ Fulfillment

ZILBRYSQ Fulfillment Pathways	3
Enrolling in ZILBRYSQ REMS	6
REMS Vaccination Requirements	9

## Product Information, Dosing, and Administration

Product Information and Dosing	11
Information Patients Need to Know Before Self-injecting ZILBRYSQ	12
How Patients Can Self-inject ZILBRYSQ	13

## Support

Personalized Support for ZILBRYSQ Patients	14
--	----

## Important Safety Information

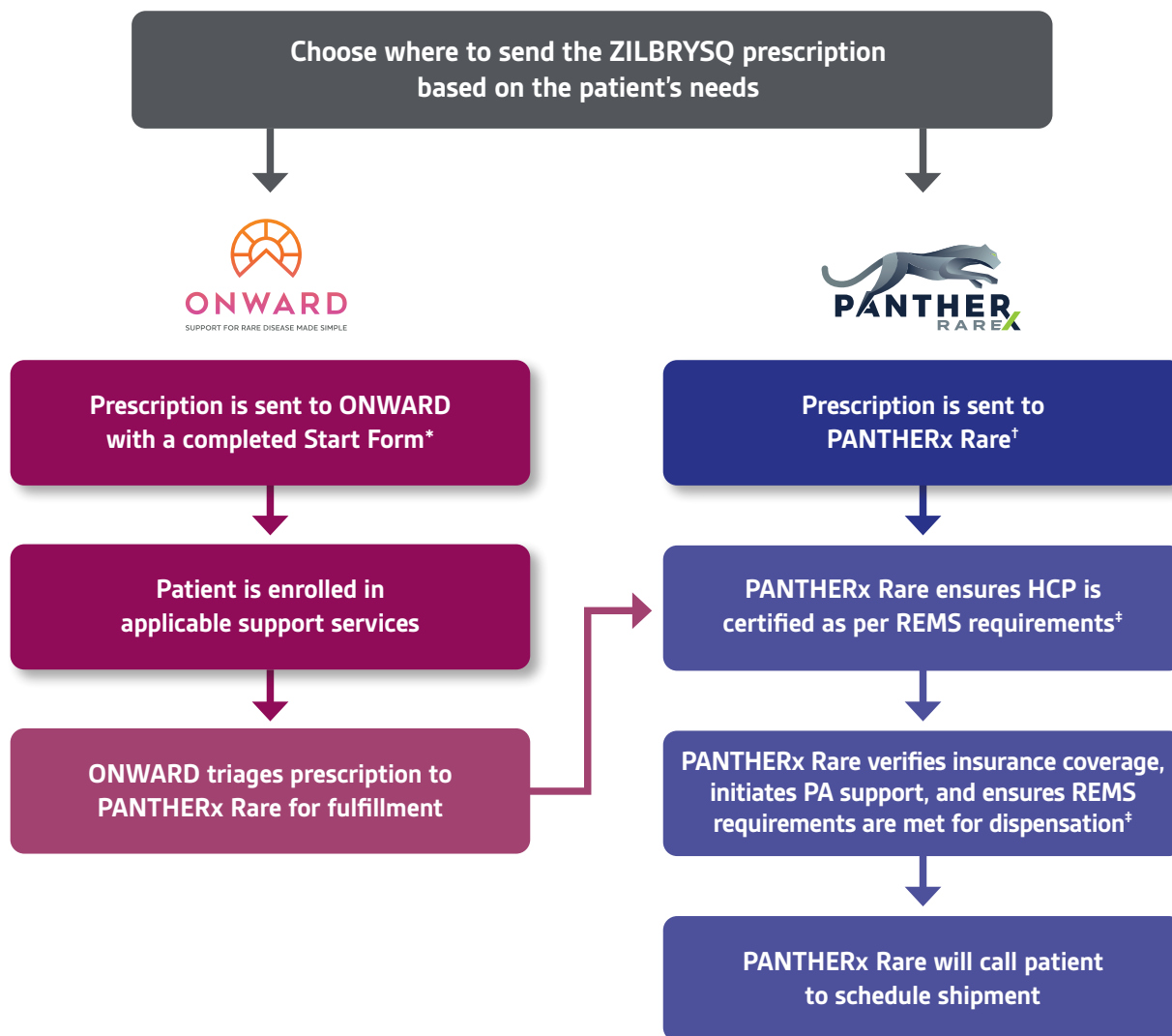
15

REMS=Risk Evaluation and Mitigation Strategy.

Please refer to the full Important Safety Information on pages 15 and 16.  
Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).

# ZILBRYSQ Fulfillment Pathways

ZILBRYSQ must be obtained through PANTHERx Rare, the authorized specialty pharmacy. Note that you may send the prescription for ZILBRYSQ to PANTHERx Rare or ONWARD®, UCB's personalized patient support program. ONWARD will ensure your patient's prescription is shared with PANTHERx Rare for fulfillment. Depending on where the prescription is sent, the process slightly differs. See the fulfillment pathways below and use this guide to help navigate accessing ZILBRYSQ for your patients.



**Please note:** If the Start Form is sent directly to PANTHERx Rare and patient consent is provided, PANTHERx Rare will contact the patient to enroll in applicable ONWARD support services. If patient consent is not provided OR if the prescription was sent without a Start Form, PANTHERx Rare will educate the patient on ONWARD services and transfer the patient to ONWARD if the patient agrees.

\*The Start Form is required to submit a prescription directly to ONWARD and is used to enroll patients in the ONWARD Patient Support Program for access to important resources and support.

†PANTHERx Rare accepts prescriptions in multiple formats: eRx, Start Form, phone, and fax.

‡**Please note:** ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS, because of the risk of serious meningococcal infections. HCPs prescribing ZILBRYSQ must enroll in the REMS and complete ZILBRYSQ REMS training to become registered as a certified provider. To learn more, see pages 6 and 7.

eRx=electronic prescription; HCP=healthcare professional; PA=prior authorization; REMS=Risk Evaluation and Mitigation Strategy.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).**

## Steps to Accessing ZILBRYSQ for Your Patients

### 1 Set expectations with your patients

- ☐ Collect information that may be required by your patient's health plan before approving ZILBRYSQ (eg, copy of your patient's insurance cards, appropriate ICD-10-CM diagnosis code(s), documented prescription/medication order, use of prior medications)
  - Reference the "Prior Authorization Checklist" for more information if a PA is required. PANTHERx Rare will work with your office during the PA approval process
- ☐ Inform your patient on next steps:
  - ONWARD will contact your patient to enroll in applicable support services
  - PANTHERx Rare will call your patient to schedule a shipment of ZILBRYSQ (see Step 4 on the next page)
    - If applicable, communicate with your patient that they can obtain ZILBRYSQ from PANTHERx Rare even if their health insurance has a preferred specialty pharmacy

### 2 Ensure REMS requirements are met ([see page 8](#) ▶)

- ☐ Enroll in the ZILBRYSQ REMS<sup>1</sup>
- ☐ At least 2 weeks prior to the first dose of ZILBRYSQ, complete or update meningococcal vaccinations if needed, according to the full ZILBRYSQ Prescribing Information, to mitigate the risk of serious meningococcal infections.<sup>1</sup> For more information, [see page 9](#) ▶

### 3 Send prescription

- ☐ Determine dosage based on patient weight. For information on recommended doses, [see page 11](#) ▶
- ☐ Send the prescription for ZILBRYSQ to PANTHERx Rare, the authorized specialty pharmacy:

ePrescribe	Fax	Phone
NPI #1659762524*	1-412-567-6135	1-833-418-7760

\*Use this NPI number when submitting a prescription electronically to PANTHERx Rare.

OR

- ☐ Send the prescription and a completed Start Form to ONWARD. ONWARD will ensure the prescription is sent to PANTHERx Rare

ACIP=Advisory Committee on Immunization Practices; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NPI=National Provider Identifier; PA=prior authorization; REMS=Risk Evaluation and Mitigation Strategy.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).**

## Steps to Accessing ZILBRYSQ for Your Patients (cont'd)

### 4 Consider enrolling patients in ONWARD

- ☐ If not previously initiated, consider enrolling your patients in ONWARD by filling out the ONWARD Start Form when prescribing. ONWARD offers patients a wide range of support to help them throughout ZILBRYSQ therapy. For more information, [see page 14](#) ▶
- ☐ Inform patients to expect a call from ONWARD (1-844-669-2731) and/or PANTHERx Rare (1-833-418-7760) to confirm their enrollment in support services and schedule their shipment

### 5 Provide self-injection training

- ☐ Train the patient and/or caregiver in subcutaneous injection technique prior to the patient's first ZILBRYSQ dose ([see page 12](#) ▶)
  - The patient may self-inject ZILBRYSQ at home or elsewhere after training<sup>1</sup>
  - Supplemental virtual injection training may be scheduled through ONWARD or PANTHERx Rare\* if requested by the patient

<sup>\*</sup>To access virtual injection training through ONWARD, the patient must be enrolled in patient support services by providing consent on the ONWARD Start Form.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).**

ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS, because of the risk of serious meningococcal infections.<sup>1</sup> HCPs must enroll in and be certified in the REMS in order to prescribe ZILBRYSQ.<sup>1</sup> Visit [ZILBRYSQREMS.com](http://ZILBRYSQREMS.com) and complete the following steps to become certified.

## 1 Become certified to prescribe

- Review the ZILBRYSQ Prescribing Information
- Review the following:
  - Healthcare Provider Safety Brochure
  - Patient Guide
  - Patient Safety Card
- Agree to<sup>1</sup>:
  - Assess for unresolved serious *Neisseria meningitidis* infection and meningococcal vaccination status
  - Complete or update meningococcal vaccinations if needed, according to the full ZILBRYSQ Prescribing Information
  - Counsel and provide the patient with the Patient Safety Card and Patient Guide
- Enroll by completing and submitting the **Prescriber Enrollment Form** to ZILBRYSQ REMS by
  - Clicking “Start Online Prescriber Enrollment” at [ZILBRYSQREMS.com](http://ZILBRYSQREMS.com); or
  - Scanning and emailing the form to [ZILBRYSQREMS@ppd.com](mailto:ZILBRYSQREMS@ppd.com); or
  - Faxing the form to 1-877-411-3609

## 2 Before starting a patient on ZILBRYSQ<sup>1</sup>

- Assess the patient for unresolved serious *Neisseria meningitidis* infection
  - DO NOT initiate ZILBRYSQ in a patient with an unresolved serious *Neisseria meningitidis* infection
- Assess the patient's vaccination status for meningococcal vaccines against serogroups A, C, W, Y, and B and complete or update vaccinations as needed at least 2 weeks prior to the first dose of ZILBRYSQ according to the full ZILBRYSQ Prescribing Information for meningococcal vaccinations in patients receiving a complement inhibitor
  - If the patient is not up to date with meningococcal vaccines at least 2 weeks prior to initiation of treatment and must start ZILBRYSQ urgently, provide the patient with a prescription for antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible

ACIP=Advisory Committee on Immunization Practices; HCP=healthcare professional; REMS=Risk Evaluation and Mitigation Strategy.

Please refer to the full Important Safety Information on pages 15 and 16.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](http://ZILBRYSQhcp.com).

### 2 Before starting a patient on ZILBRYSQ<sup>1</sup> (cont'd)

- Counsel the patient about the risk of serious meningococcal infections and using the Patient Safety Card and Patient Guide
  - Counsel the patient to carry the Patient Safety Card at all times during and for 2 months following treatment with ZILBRYSQ
  - Provide a copy of the materials to the patient

### 3 While the patient is on ZILBRYSQ<sup>1</sup>

- Closely monitor the patient for early signs and symptoms of meningococcal infection and evaluate the patient immediately if infection is suspected
- Consider interruption of ZILBRYSQ in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated
- Inform patients of the requirement to be revaccinated according to current ACIP recommendations for meningococcal infection while on ZILBRYSQ therapy

### 4 At all times<sup>1</sup>

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. by calling 1-844-599-2273 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

ACIP=Advisory Committee on Immunization Practices; FDA=US Food and Drug Administration.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](http://ZILBRYSQhcp.com).**

**Notable requirements of the ZILBRYSQ REMS include the following<sup>1</sup>:**



### **Prescribers MUST:**

- Enroll in the REMS
- Counsel patients about the risk of serious meningococcal infection
- Provide the patients with the REMS educational materials
- Assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B)
  - Vaccinate if needed according to current ACIP recommendations 2 weeks prior to the first dose of ZILBRYSQ
- Provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently and a patient is not up to date with meningococcal vaccines according to the full ZILBRYSQ Prescribing Information at least 2 weeks prior to the first dose of ZILBRYSQ



### **Pharmacies that dispense ZILBRYSQ MUST:**

- Be certified in the REMS and verify that prescribers are certified



### **Patients MUST:**

- Receive counseling from the prescriber. Counseling points may include:
  - The need to receive meningococcal vaccines (against serogroups A, C, W, Y, and B) per the full ZILBRYSQ Prescribing Information
  - The need to take antibiotics as directed by the prescriber
  - Signs and symptoms of meningococcal infection
- Be instructed to carry the Patient Safety Card with them at all times during and for 2 months following treatment discontinuation with ZILBRYSQ



Scan the QR code to visit [ZILBRYSQREMS.com](https://ZILBRYSQREMS.com) or  
call 1-877-414-8353 for questions or to learn more

REMS=Risk Evaluation and Mitigation Strategy.

**Please refer to the full Important Safety Information on pages 15 and 16.**

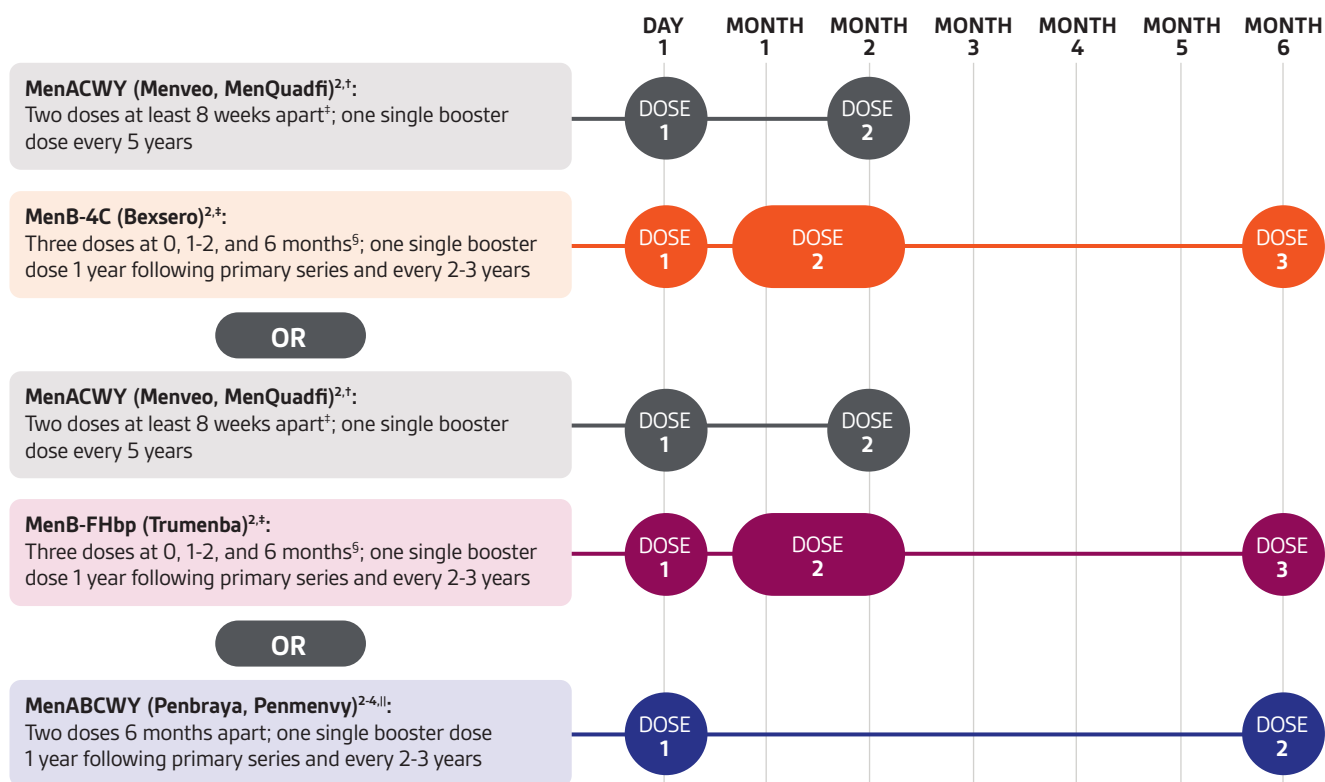
**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://ZILBRYSQhcp.com).**

## ZILBRYSQ REMS Vaccination Requirements

Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to the full ZILBRYSQ Prescribing Information at least 2 weeks prior to the first dose of ZILBRYSQ.<sup>1</sup> The 2025 ACIP guidelines recommend that patients with persistent complement component deficiency or patients receiving complement inhibitors, including ZILBRYSQ, follow the meningococcal vaccination schedule below.<sup>2</sup>

### Complete or update meningococcal vaccines ≥2 weeks before starting ZILBRYSQ<sup>1</sup>

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with meningococcal vaccines, provide the patient with antibacterial drug prophylaxis\* and administer these vaccines as soon as possible.<sup>1</sup>



Minimum time for complete vaccination: at least 6 months<sup>2-4</sup>

**Patients should complete or update meningococcal vaccination (serogroups A, C, W, Y, and B) at least 2 weeks prior to receiving the first dose of ZILBRYSQ<sup>1</sup>**

\*Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.<sup>5</sup>

<sup>†</sup>MenACWY-D (Menactra) was discontinued in 2022. For MenACWY vaccines, the same vaccine product is recommended, but not required, for all doses.<sup>5,6</sup> <sup>‡</sup>MenB vaccines are not interchangeable; the same brand must be used for each dose of the primary series and all booster doses.<sup>2</sup> If dose 2 was administered at least 6 months after dose 1, then dose 3 is not needed. If dose 3 is administered earlier than 4 months after dose 2, a fourth dose should be administered at least 4 months after dose 3.<sup>2,11</sup> <sup>§</sup>Adults may receive a single dose of Penbraya or Penmenv as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.<sup>2,5</sup> <sup>||</sup>ACIP=Advisory Committee on Immunization Practice; MenABCWY=meningococcal serogroups ABCWY; MenACWY=meningococcal serogroups ACWY; MenB=meningococcal serogroup B; MenB-4C=4-component meningococcal group B; MenB-FHbp=meningococcal serogroup B factor H binding protein; REMS=Risk Evaluation and Mitigation Strategy.

Please refer to the full Important Safety Information on pages 15 and 16.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).

## REMS Support

Committed to patient safety, UCB is working with PANTHERx Rare to help patients access their REMS-required vaccines.

### Vaccination Status and Tracking

- Upon receipt of prescription, PANTHERx Rare may contact your office to document the patient's vaccination history (if not provided already)
- If vaccination is required, PANTHERx Rare will track timing for subsequent vaccinations and boosters to communicate scheduled doses with the patient and your office as appropriate

### Vaccination Support

- To support patient safety, PANTHERx Rare will:
  - Monitor all aspects of the patient journey as it relates to accessing vaccines as needed for the REMS requirements
  - Help facilitate vaccination access in alignment with a patient's benefit design by identifying local resources (retail/community pharmacies or local health departments) within a patient's geographic location that can administer the REMS-required vaccines to the patient
  - Follow up with you to document vaccinations received in patient records as appropriate

REMS=Risk Evaluation and Mitigation Strategy.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).**

## Product Information



The ZILBRYSQ injection prefilled syringe contains a sterile, preservative-free, clear to slightly opalescent, colorless solution.

Each single-dose prefilled syringe consists of a 1 mL glass syringe with a 29-gauge ½-inch needle, a needle safety guard, and a needle cover. The ZILBRYSQ prefilled syringe components are not made with natural rubber latex.

## National Drug Code (NDC)

ZILBRYSQ is available as follows:

NDC	Pack size*	Dose
50474-990-80	28 single-dose prefilled syringes	16.6 mg/0.416 mL
50474-991-80	28 single-dose prefilled syringes	23 mg/0.574 mL
50474-992-80	28 single-dose prefilled syringes	32.4 mg/0.81 mL

\*Pack consists of 4 cartons, each containing 7 syringes for a total of 28 syringes.

## Dosing

**The recommended dosage of ZILBRYSQ is based on body weight**

ZILBRYSQ is supplied in cartons with single-dose prefilled syringes.

Body weight of patient	Once-daily dosage	Plunger color
<56 kg	16.6 mg/0.416 mL	Rubine red
≥56 kg to <77 kg	23 mg/0.574 mL	Orange
≥77 kg	32.4 mg/0.81 mL	Dark blue

## IMPORTANT SAFETY INFORMATION (cont'd)

### CONTRAINDICATIONS

ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

Please refer to the full Important Safety Information on pages 15 and 16.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).

# Information Patients Need to Know Before Self-injecting ZILBRYSQ<sup>1</sup>

ZILBRYSQ is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject ZILBRYSQ after training in subcutaneous injection technique. Prior to your patient's first dose, train the patient and/or caregiver in subcutaneous injection technique of ZILBRYSQ according to the "Instructions for Use" outlined in the [Prescribing Information](#). See preparation and administration instructions below and on the next page.

## Preparation prior to administration



Patients may store ZILBRYSQ prefilled syringes in a refrigerator in the original carton or at room temperature in the original carton for up to 3 months or until the expiration date, whichever occurs first



If stored in the refrigerator:

- Before injecting, take 1 ZILBRYSQ prefilled syringe out of the refrigerator and place it on a clean, flat surface. Allow ZILBRYSQ to reach room temperature out of direct sunlight by waiting 30 to 45 minutes before injecting. Do not heat or place in microwave
- Immediately return the carton with the other prefilled syringes to the refrigerator



If stored at room temperature:

- Remove 1 ZILBRYSQ prefilled syringe from the carton
- Do not return ZILBRYSQ to the refrigerator after it has been stored at room temperature



Visually inspect ZILBRYSQ for particulate matter and discoloration prior to administration

- ZILBRYSQ is a clear to slightly opalescent, colorless solution. Do not use if the solution contains visible particles, is cloudy, or if foreign particulate matter is present
- ZILBRYSQ does not contain preservatives; unused portions of drug remaining in the syringe should be discarded
- Each prefilled syringe is for single use only



## Injection Training

- Training kits are available for patients. Reach out to your UCB Account Executive for additional information if interested
- ONWARD offers Virtual Refresher Injection Training for enrolled patients. PANTHERx Rare also provides virtual injection training and administration technique counseling for patients. Inform patients that they can schedule refresher trainings as needed

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

#### Serious Meningococcal Infections

ZILBRYSQ, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of ZILBRYSQ treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.

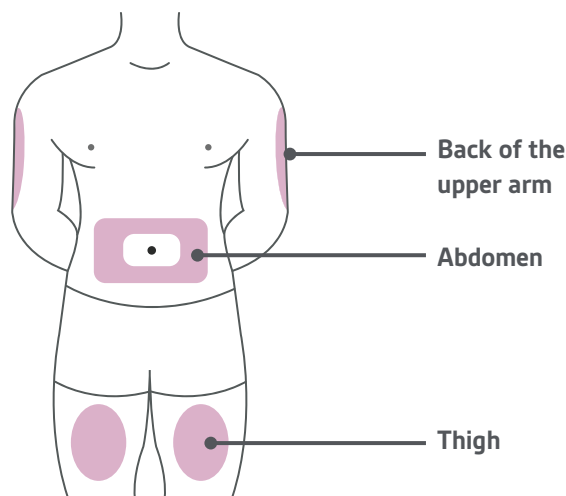
Please refer to pages 13, 15, and 16 for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).

## Administration considerations

**Administer ZILBRYSQ subcutaneously into areas of the abdomen, thighs, or back of the upper arms that are not tender, bruised, red, or hard**

- Avoid injecting into areas with scars or stretch marks
- Rotate injection sites for each administration
- **Please note:** Administration of ZILBRYSQ in the upper, outer arm should be performed by a caregiver



- When using ZILBRYSQ prefilled syringes, inject the full contents of the single-dose prefilled syringe
- Discard ZILBRYSQ prefilled syringe after use. Do not reuse
- **Instruct the patient that the daily dose should be administered at approximately the same time each day**
  - If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time. Do not administer more than 1 dose per day

**For more information on preparation and administration, please visit [ZILBRYSQhcp.com/dosing](https://ZILBRYSQhcp.com/dosing) and refer to the Instructions for Use**

ACIP=Advisory Committee on Immunization Practices.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Serious Meningococcal Infections (cont'd)

Complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://ZILBRYSQhcp.com).**



**ONWARD<sup>\*</sup>** is an individualized support experience built to help patients through every step of their ZILBRYSQ treatment. With ONWARD, prescribed patients living with generalized myasthenia gravis (gMG) will have access to important resources, including:



Communication with a dedicated Care Coordinator to provide personalized support<sup>†</sup>



Help in reviewing insurance coverage and potential financial assistance options



Tools and resources to start and stay on treatment, as prescribed



Help tracking symptoms and ongoing treatment support

## Consider enrolling your patients in ONWARD when prescribing ZILBRYSQ

Fill out the Start Form or use the online portal to enroll patients at your office

- ✓ Patients are automatically enrolled if the completed Start Form is sent to ONWARD
- ✓ If the Start Form and prescription are sent directly to PANTHERx Rare and patient consent is provided, PANTHERx Rare will transfer applicable information to ONWARD for enrollment

**Inform patients to expect a call from an ONWARD Care Coordinator<sup>‡</sup> (844-669-2731) to discuss the support services being requested.**

### Patient Support

If you have questions about getting your ZILBRYSQ patients started in the ONWARD<sup>®</sup> Patient Support Program, please visit [ucbONWARD.com](https://ucbONWARD.com) to access resources for healthcare professionals or contact your Rare Reimbursement Executive for assistance.

<sup>\*</sup>ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.

<sup>†</sup>ONWARD does not provide medical advice and does not replace the care of the healthcare professional. Care Coordinators will refer patients to their healthcare provider for any treatment-related questions.

<sup>‡</sup>Please note that when patients receive this call, they may see "ONWARD" on their caller ID.

**Please refer to the full Important Safety Information on pages 15 and 16.**

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://ZILBRYSQhcp.com).**

## IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

### WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.
- Patients receiving ZILBRYSQ are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

### CONTRAINDICATIONS

ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

### WARNINGS AND PRECAUTIONS

#### Serious Meningococcal Infections

ZILBRYSQ, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of ZILBRYSQ treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor.

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Consider interruption of ZILBRYSQ in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

Please refer to the next page for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](https://www.zilbrysqhcp.com).

## IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### ZILBRYSQ REMS

Due to the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS.

Under the ZILBRYSQ REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines. Additional information on the REMS requirements is available at [www.ZILBRYSQREMS.com](http://www.ZILBRYSQREMS.com) or 1-877-414-8353.

#### Other Infections

Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported in patients treated with complement inhibitors. ZILBRYSQ blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Administer vaccinations for the prevention of *Streptococcus pneumoniae* infection according to ACIP recommendations. Patients receiving ZILBRYSQ are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

#### Pancreatitis and Other Pancreatic Conditions

Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Patients should be informed of this risk before starting ZILBRYSQ. Obtain lipase and amylase levels at baseline before starting treatment with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

### ADVERSE REACTIONS

In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of gMG patients treated with ZILBRYSQ) were injection site reactions, upper respiratory tract infections, and diarrhea.

**Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit [ZILBRYSQhcp.com](http://ZILBRYSQhcp.com).**

**For more information about ZILBRYSQ, visit [ZILBRYSQhcp.com](http://ZILBRYSQhcp.com).**

**For additional information, contact UCBCares® at 1-844-599-CARE (2273).**

ACIP=Advisory Committee on Immunization Practices; gMG=generalized myasthenia gravis.

**References:** 1. ZILBRYSQ [prescribing information]. Smyrna, GA: UCB, Inc. 2. Centers for Disease Control and Prevention. Recommended adult immunization schedule for ages 19 or older; 2025 US. Available at: <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf>. Published November 11, 2024. Accessed March 13, 2025. 3. PENBRAYA [prescribing information]. New York, NY: Pfizer Inc. 4. PENMENVY [prescribing information]. Durham, NC: GlaxoSmithKline. 5. Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Morb Mortal Wkly Rep*. Available at: <https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf>. Published September 25, 2020. Accessed March 13, 2025. 6. Connecticut Department of Public Health. Transition from Menactra to MenQuadfi meningococcal conjugate vaccine. Available at: [https://portal.ct.gov/immunization/-/media/departments-and-agencies/dph/dph/infectious\\_diseases/immunization/cvp-2020/2022-cvp-communications/update-menactra-discontinuation-2-24-22.pdf](https://portal.ct.gov/immunization/-/media/departments-and-agencies/dph/dph/infectious_diseases/immunization/cvp-2020/2022-cvp-communications/update-menactra-discontinuation-2-24-22.pdf). February 24, 2022. Accessed March 13, 2025.



ZILBRYSQ®, ONWARD®, and UCBCares® are registered trademarks of the UCB Group of Companies.  
©2025 UCB, Inc., Smyrna, GA 30080. All rights reserved.  
US-ZL-2500143 | May 2025