ZILBRYSQ®
(zilucoplan) Injection

GIVE YOUR ADULT PATIENTS THE POWER TO TAKE CHARGE OF gMG EVERY DAY[1,2]

Getting started with ZILBRYSQ

ZILBRYSQ is the first and only self-administered complement C5 inhibitor for adult patients with **anti-AChR antibody positive (Ab+) generalized myasthenia gravis (gMG).**[1,2]

C5=complement component 5.

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.

Please see full Important Safety Information, including Boxed Warning for serious meningococcal infections.

How to initiate treatment with ZILBRYSQ

Get your patients started on ZILBRYSQ with these 3 steps

ZILBRYSQ is only available through the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy), due to the risk of serious meningococcal infections.[1]

STEP 1

Enroll in the ZILBRYSQ REMS[1]

Before prescribing ZILBRYSQ to patients, healthcare providers must become certified in the ZILBRYSQ REMS, which is intended to mitigate the risk of serious meningococcal infections.

Check the vaccination schedule to determine if it is necessary to complete or update the meningococcal vaccination series for your patient.[1] See the details for REMS on pages 12-13 of this guide.

Complete or update meningococcal vaccinations at least 2 weeks prior to starting ZILBRYSQ.

See the details for vaccination on pages 14-15 of this guide.

To learn more or become certified, please visit ZILBRYSQREMS.com or call 1-877-414-8353.

To learn more about starting patients on ZILBRYSQ, please visit **ZILBRYSQHCP.com/learnmore**

STEP 2

Complete the ONWARD® Start Form to prescribe

To get an eligible patient started on ZILBRYSQ, complete the ONWARD Start Form, either electronically or by filling out the PDF and faxing it to ONWARD. ONWARD can collect the patient's HIPAA authorization electronically, if needed. Visit ZILBRYSQHCP.com/learnmore to download the form.

If you have questions about starting your patients in ONWARD, visit ucbONWARD.com/hcp/ZILBRYSQ or contact your Rare Reimbursement Executive (RRE).

STEP 3

Your patients are ready with ONWARD!

ONWARD helps patients throughout their ZILBRYSQ treatment journey by providing education and support from initiation through continuation of treatment with services such as*:

- A 24-hour turnaround time from intake to prescription triage with a completed Start Form (includes Financial Assistance eligibility assessment)
- A dedicated Care Coordinator to help eligible patients start and stay on their prescribed treatment.† The Care Coordinator can address patients' questions about vaccination, self-injection, and affordability. Additionally, the Care Coordinator is able to communicate with patients using their preferred channel (phone, video chat, email, or text)
- A demonstration device and refresher injection coaching with a Care Coordinator through video chat to help them prepare to self-administer ZILBRYSQ. Patients can find the full list of steps in the Instructions for Use

*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.

†ONWARD does not provide medical advice and does not replace the care of the healthcare provider. Care Coordinators will refer you to your healthcare provider for any treatment-related questions.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

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

Please see full Important Safety Information and the full Prescribing Information.

ZILBRYSQ® (zilucoplan) Injection

Patients can take charge of their gMG, at home or away[1,2]

ZILBRYSQ is a once daily self-administered, subcutaneous injection that fits into patients' daily lives[1,2]

- Ability to use at **home or away**
- **Once daily** administration
- **Ready-to-use** prefilled syringe
- Keep at room temp for **up to 3 months***

Pharmacy must refrigerate until ready to dispense ZILBRYSQ.†

ZILBRYSQ has 3 available doses based on body weight[1]

Body weight of patient	Dose
Less than 56 kg (123 lbs)	**16.6 mg/0.416 mL**
56 kg to less than 77 kg (123–170 lbs)	**23 mg/0.574 mL**
77 kg and above (>170 lbs)	**32.4 mg/0.81 mL**

Color of packaging and plunger differ by dose.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

*ZILBRYSQ prefilled syringes may be stored at room temperature up to 86°F (30°C) in the original carton for a single period of up to 3 months. Once ZILBRYSQ has been stored at room temperature, write the date removed from the refrigerator in the space provided on the carton and discard if not used within 3 months or if the expiration date has passed, whichever occurs first. If stored in the refrigerator, ZILBRYSQ may take 30 to 45 minutes to warm up to room temperature before injecting. Do not return ZILBRYSQ to the refrigerator after it has been stored at room temperature.[1]

†Pharmacy must keep ZILBRYSQ refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton until dispensing.[1]

The Self-Injection Assessment Questionnaire© (SIAQ) was administered to patients who participated in RAISE-XT[3‡]

89% (n=56) were satisfied or very satisfied with the time it took to self-administer ZILBRYSQ

84% (n=53) were very or extremely confident in their ability to self-administer ZILBRYSQ

In addition, a majority of the patients surveyed believe that self-injections with ZILBRYSQ were convenient and easy to administer.[3] Patients or caregivers may inject ZILBRYSQ after proper training by a healthcare professional.[1]

§SIAQ is a self-administered patient-reported outcome survey used to assess the self-injection experience of patients in the RAISE-XT trial. Patients from RAISE-XT who participated in SIAQ received dedicated device training for administration of ZILBRYSQ. The survey was completed at home, directly after self-injection, in 2 assessments approximately 2 weeks apart (first assessment n=63, second assessment n=52).[3]

SIAQ is composed of 21 questions spanning 6 domains; 5 of these domains are termed causal domains (feelings about injections, self image, self-confidence, injection site reactions, and ease of use) since these are considered determining factors of the sixth domain: satisfaction with self-injection.[3,4]

RAISE-XT post hoc analysis: ZILBRYSQ compliance data[5]

Over a median exposure of 2.2 years (range: 0.1-5.6), 95% (189/199) of patients reported taking >95% of their medication.

99.2% In total (n=199), patients reported taking a mean percentage of 99.2% of their medication

Compliance data were analyzed for 199 patients from RAISE-XT. The mean percentage of medication taken was analyzed post hoc for the overall population and subgroups§ of:

- Age (<65 and ≥65 years)
- Sex (male and female)
- Disease duration (<median and ≥median)
- Baseline MG-ADL score (≤9 and ≥10)

Study limitations:

RAISE-XT was designed to evaluate safety and was not placebo controlled. The percentage of medication taken was not a pre-specified endpoint. Results should be interpreted with caution. Clinical significance has not been established.

‡The primary objective of RAISE-XT was to evaluate the long-term safety and tolerability of ZILBRYSQ in study participants with gMG. Long-term efficacy was also studied through multiple measures as select secondary endpoints. The open-label extension is an ongoing study with the current interim data cutoff (May 11, 2023) at Week E84.[6,7]

§Data for the subgroups were consistent with those of the overall population. Mean percentage of medication taken for all subgroups was ≥98.4% of doses.[5]

Please see full Important Safety Information and the full Prescribing Information.

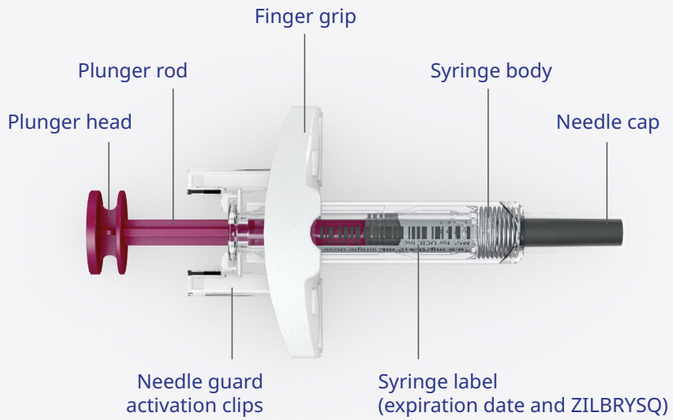
ZILBRYSQ® (zilucoplan) Injection

Administering ZILBRYSQ

Once daily administration with a ready-to-use prefilled syringe[1]

Provide proper training to patients and/or caregivers on the subcutaneous injection technique of ZILBRYSQ according to the Instructions for Use.

ZILBRYSQ prefilled syringe parts



Color of plunger differs by dose.
All ZILBRYSQ single-dose prefilled syringes have a 29-gauge 1/2 inch needle.

Visit **ZILBRYSQ.com/learnhow** for injection training resources, including the ZILBRYSQ Injection Training Video

IMPORTANT SAFETY INFORMATION (cont'd)

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.

ZILBRYSQ can be administered subcutaneously in 1 of the following areas:

- Front of the thighs
- Abdomen, except for the 2-inch area around the belly button (navel)
- Back of the upper arms (only if administered by a caregiver)

Do not administer ZILBRYSQ if the injection site is:

- Tender
- Bruised
- Red
- Hard
- Swollen
- On a scar
- On a stretch mark

Areas with scars or stretch marks should be avoided. Rotate injection sites for each administration.*

Patients can find the full list of steps in the Instructions for Use.

Direct patients to administer ZILBRYSQ at approximately the same time each day. If a dose is missed, patients should administer the dose as soon as possible. ZILBRYSQ should only be administered once per day.

When using ZILBRYSQ prefilled syringes, patients should inject the full contents of the single-dose prefilled syringe and discard after use. Do not reuse.

The most common adverse reactions (reported in at least 10% of patients treated with ZILBRYSQ) were injection site reactions, upper respiratory tract infections, and diarrhea.

*If the same injection site is used, it should be at least 1 inch from the spot used before.

Please see full Important Safety Information and the full Prescribing Information.

ZILBRYSQ® (zilucoplan) Injection

How to properly store and dispose of ZILBRYSQ[1]

Offering 2 storage options for patients to use at home or away

Storing ZILBRYSQ

ZILBRYSQ has the ability to be stored at room temperature in the original carton for up to 3 months if refrigeration isn't available. Remember to always store ZILBRYSQ in the original carton when not in use.

If stored in the refrigerator:

- Before injecting, take the prefilled syringe carton out of the refrigerator
- Remove 1 prefilled syringe from the carton and place the rest of the prefilled syringes in the carton back into the refrigerator
- Let the prefilled syringe warm up to room temperature on a clean, flat surface for 30 to 45 minutes. Do not warm the prefilled syringe in any other way (for example in a microwave, in hot water, or in direct sunlight)

If stored at room temperature:

- Remove 1 prefilled syringe from the carton
- Do not return ZILBRYSQ to the refrigerator after it has been stored at room temperature
- Discard if not used within 3 months or if the expiration date has passed, whichever occurs first

Disposing of ZILBRYSQ

Each prefilled syringe is for single use only and must be disposed of properly after use.

Patients must dispose of used ZILBRYSQ prefilled syringes into a sharps disposal container right away. If they do not have an FDA-cleared sharps disposal container, they may use a household container that meets select characteristics.

When their sharps disposal container is almost full, please advise your patients to follow their community guidelines for the right way to dispose of their sharps disposal container.

To learn more about storage and disposal, please visit **ZILBRYSQHCP.com/takecharge**

ZILBRYSQ® (zilucoplan) Injection

Personalized support for your patients with gMG

ZILBRYSQ patient support with ONWARD®

ONWARD is an individualized support experience built to help your patients who have been prescribed ZILBRYSQ for treatment of generalized myasthenia gravis (gMG) throughout every step of their treatment journey.* With ONWARD, your prescribed patients living with gMG will be paired with a dedicated clinically trained Care Coordinator† who will provide tailored support based on each patient's unique needs.

ONWARD provides:

Support for your eligible patient:

- A dedicated clinically trained Care Coordinator to provide personalized support
- One-on-one injection treatment support including training, tips, and reminders
- Help in reviewing potential financial assistance options
- Tools and resources to start and continue prescribed treatment
- Help tracking symptoms and ongoing treatment support
- Refresher injection coaching to help patients prepare to self-administer ZILBRYSQ

Resources for you:

- ONWARD Start Form – to get eligible patients started
- e-Start Form – electronic form to get eligible patients started
- Downloadable materials to share with your patients
- Coordination with a dedicated specialty pharmacy that handles prescriptions, logistics, and timely delivery of medication to your patients

To learn more about ONWARD, please contact your Rare Reimbursement Executive (RRE) or visit **ZILBRYSQHCP.com/ONWARD**

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†ONWARD does not provide medical advice and does not replace the care of the healthcare provider. Care Coordinators will refer you to your healthcare provider for any treatment-related questions.

ONWARD
PERSONALIZED SUPPORT DESIGNED TO MOVE YOU FORWARD

Download the Start Form now by visiting **ZILBRYSQHCP.com/DWNLD-startform**

Committed to patient safety, UCB is working with PANTHERx Rare as the ZILBRYSQ exclusive dispensing pharmacy 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 your office to document vaccinations received in patient records as appropriate

To contact PANTHERx Rare, call 833-418-7760 and follow the prompts to speak with a pharmacist.

Please see full Important Safety Information and the full Prescribing Information.

ZILBRYSQ® (zilucoplan) Injection

ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy)[1]

ZILBRYSQ is only available through the ZILBRYSQ REMS, due to the risk of serious meningococcal infections

What is REMS?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the FDA to ensure that the benefits of the drug outweigh the risks.[8]

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.

All healthcare providers who prescribe ZILBRYSQ must be certified in the ZILBRYSQ REMS. Certification includes a review of REMS educational materials and enrollment into the ZILBRYSQ REMS, which can be found by visiting www.ZILBRYSQREMS.com.

Requirements of the ZILBRYSQ REMS include:

- Prescribers must counsel patients about the risk of serious meningococcal infection
- Prescribers must provide the patients with the REMS educational materials
- Prescribers must assess patient vaccination status for meningococcal vaccines (against serogroups A, C, W, Y, and B) and vaccinate if needed according to current ACIP recommendations two weeks prior to the first dose of ZILBRYSQ
- Patients must be instructed to carry the Patient Safety Card with them at all times during and for 2 months following treatment discontinuation with ZILBRYSQ

ZILBRYSQ vaccination requirements

- Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of ZILBRYSQ therapy

Note: ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information.

Please see the following page for the vaccination schedule

- 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
- The optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ZILBRYSQ
- 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 patients immediately if infection is suspected

INSTRUCT patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early

INFORM patients of early signs and symptoms of meningococcal infection

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 see full Important Safety Information and the full Prescribing Information.

ZILBRYSQ® (zilucoplan) Injection

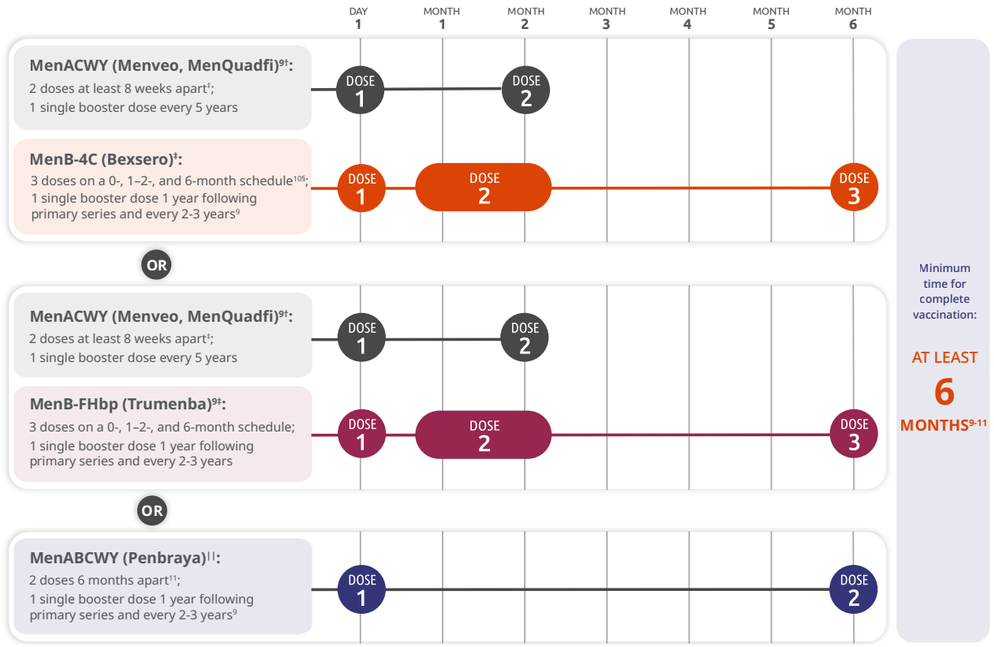
Required vaccines before starting ZILBRYSQ

Complete or update meningococcal vaccinations for patients prior to starting ZILBRYSQ[1]

The ACIP recommends patients with persistent complement component deficiency or patients receiving complement inhibitors follow the meningococcal vaccination schedule below.[1,9]

Complete or update both vaccines ≥2 weeks before starting ZILBRYSQ[1]

If ZILBRYSQ must be initiated immediately for a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.[1]*



*Several antibiotics are available for the treatment of meningococcal disease, including ceftriaxone, cefotaxime, and, when the diagnosis is confirmed, penicillin.[12]

† MenACWY-D (Menactra) was discontinued in 2022. For MenACWY vaccines, the same vaccine product is recommended, but not required, for all doses.[12,13]

‡ MenB vaccines are not interchangeable; the same brand must be used for each dose of the primary series and all booster doses.[9]

§ 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.[9]

|| Adults may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.[9]

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.[1]

Revaccinate patients in accordance with ACIP recommendations considering the duration of ZILBRYSQ therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine Prescribing Information.

The optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including ZILBRYSQ.

Please see the respective meningococcal vaccine Prescribing Information for complete details, including vaccine Warnings, Precautions, and Contraindications.

The benefits and risks of treatment with ZILBRYSQ, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by *Neisseria meningitidis*.

To learn more about the vaccination schedule,
visit **ZILBRYSQHCP.com/learnmore**

Please see full Important Safety Information and the full Prescribing Information.

ZILBRYSQ®
(zilucoplan) Injection

Important Safety Information

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.

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.

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 serious 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** 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 see the accompanying full Prescribing Information.

References: 1. ZILBRYSQ [Prescribing Information]. Smyrna, GA: UCB, Inc. **2.** Howard JF Jr, Bresch S, Genge A, et al; RAISE Study Team. Safety and efficacy of zilucoplan in patients with generalised myasthenia gravis (RAISE): a randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Neurol.* 2023;22(5):395-406. doi:10.1016/S1474-4422(23)00080-7 **3.** Data on file. UCB, Inc. **4.** Keininger D, Coteur G. Assessment of self-injection experience in patients with rheumatoid arthritis: psychometric validation of the Self-Injection Assessment Questionnaire (SIAQ). *Health Qual Life Outcomes.* 2011;9(2):1-11. doi:10.1186/1477-7525-9-2 **5.** Ruzhansky K, Freimer M, Leite MI, et al; on behalf of the RAISE-XT study team. Compliance to daily self-administered subcutaneous zilucoplan in patients with generalized myasthenia gravis: a post hoc analysis of the RAISE-XT study. Poster presented at: American Association of Neuromuscular & Electrodiagnostic Medicine Annual Meeting; October 15-18, 2024; Savannah, GA. Poster 264. **6.** Howard JF Jr, Bresch S, Farmakidis C, et al. Long-term safety and efficacy of zilucoplan in patients with generalized myasthenia gravis: interim analysis of the RAISE-XT open-label extension study. *Ther Adv Neurol Disord*. 2024;17(3):1-16. doi:10.1177/17562864241243186 **7.** Leite MI, Bresch S, Hewamadduma C, et al; on behalf of the RAISE-XT study team. Long-term zilucoplan in generalised myasthenia gravis: 96-week follow-up interim analysis of RAISE-XT. Presented at European Academy of Neurology 2024 Annual Meeting; April 13-18, 2024; Helsinki, Finland. Presentation EPR-254. **8.** Risk Evaluation and Mitigation Strategies (REMS). US Food & Drug Administration. Updated May 16, 2023. Accessed November 20, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems **9.** Recommended adult immunization schedule for ages 19 years or older. Centers for Disease Control and Prevention. Updated June 27, 2024. Accessed November 11, 2024. https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf **10.** Bexsero [Prescribing Information]. Durham, NC; GlaxoSmithKline. **11.** Penbraya [Prescribing Information]. New York, NY; Pfizer. **12.** Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep*. 2020;69(9):1-41. doi:10.15585/mmwr.rr6909a1 **13.** Transition from Menactra to MenQuadfi meningococal conjugate vaccine. Connecticut Department of Public Health. February 24, 2022. Accessed November 1, 2023. 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

ZILBRYSQ®
(zilucoplan) Injection

Give your patients the power to take charge with ZILBRYSQ

It takes 3 steps to start your patients:

1. Enroll in the ZILBRYSQ REMS

Intended to mitigate the risk of serious meningococcal infections.

2. Complete the ONWARD® Start Form to prescribe

Fill out the ONWARD Start Form during your eligible patient's next visit or e-enroll with the online portal. Visit ZILBRYSQHCP.com/learnmore to download the form.

3. Your eligible patients are ready with ONWARD!

ONWARD is an individualized support experience built to help your patients who have been prescribed ZILBRYSQ for treatment of generalized myasthenia gravis (gMG) throughout every step of their treatment journey.* If you have any questions, visit ucbONWARD.com or contact your Rare Reimbursement Executive (RRE).

Learn more about ZILBRYSQ by visiting **ZILBRYSQHCP.com/learnmore**

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

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 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. ZILBRYSQ is available only through a restricted program called ZILBRYSQ REMS. ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection. Additional important warnings and precautions associated with ZILBRYSQ include an increased susceptibility to infections and pancreatitis and pancreatic cysts. The most common adverse reactions (≥10%) were injection site reactions, upper respiratory tract infection, and diarrhea.

INDICATION

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

*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.

Please see full **Important Safety Information** and the full **Prescribing Information**.

ZILBRYSQ®
(zilucoplan) Injection

Inspired by patients. Driven by science.