

## What is the ZILBRYSQ REMS (Risk Evaluation Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. ZILBRYSQ has a REMS because it increases your chance of getting a meningococcal infection. The infection can quickly become life threatening or fatal if not recognized and treated early. ZILBRYSQ is only available through a restricted distribution program called 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.

## What are the program requirements?

ZILBRYSQ is available exclusively through a restricted program under a REMS.

Prescribers and pharmacies must each be specially certified in order to prescribe or dispense ZILBRYSQ. Certification includes a review of REMS educational materials and enrollment into the ZILBRYSQ REMS.

### Prescribers

Healthcare Providers must be certified in the ZILBRYSQ REMS in order to prescribe ZILBRYSQ.

[Start Prescriber Enrollment](#)

### Patients

Patients must get vaccinated with meningococcal vaccines prior to starting ZILBRYSQ therapy. They must also understand the need for immediate medical attention for any signs or symptoms of meningococcal infection.

[View Patient Guide](#)

### Pharmacies

Pharmacies should designate an Authorized Representative. Authorized Representatives must be certified in the ZILBRYSQ REMS in order to prescribe ZILBRYSQ.

[Start Pharmacy Enrollment](#)

### Wholesalers and Distributors

Wholesalers, distributors, and other entities that distribute ZILBRYSQ must ensure that ZILBRYSQ is distributed only to ZILBRYSQ REMS certified pharmacies.

[List of Certified Pharmacies](#)

## Reporting Adverse Events:

Report any adverse events, including (suspected) meningococcal infections, to UCB, Inc. at 1-844-599-2273 and/or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## Advisory Committee on Immunization Practices (ACIP) Guidelines:

[ACIP recommendations](#) are periodically updated. Therefore, please check the latest recommendations to ensure the vaccination status of your patients is up to date, to minimize the increased risk of meningococcal infection associated with ZILBRYSQ therapy for your patients.

## Indication:

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

## Prescribers:

All healthcare providers who prescribe ZILBRYSQ must be certified in the REMS.

## To become certified, prescribers must:

1 - Review

2 - Agree

3 - Submit

### Review the ZILBRYSQ REMS materials:

- [Prescribing Information](#)
- [Healthcare Provider Safety Brochure](#)
- [Patient Guide](#)
- [Patient Safety Card](#)

### Agree to:

- Assess the patient for unresolved meningococcal infection.
- Assess the patient's meningococcal vaccine status (MenACWY and MenB).
- Vaccinate the patient if needed according to the current Advisory Committee on Immunization Practices recommendations.

### Submit the completed Prescriber Enrollment Form by either:

- Clicking "Start Online Prescriber Enrollment" below; or
- Scanning and emailing to ZILBRYSQREMS@ppd.com; or
- Faxing to 1-877-411-3609

### Agree to counsel patients and provide them with the:

- [Patient Guide](#)
- [Patient Safety Card](#)

Start Online  
Prescriber Enrollment

Or - Print and fax, or email to ZILBRYSQ REMS:

 [Prescriber Enrollment Form](#)

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## Pharmacies:

All pharmacies that dispense ZILBRYSQ must be certified in the REMS.

## To become certified and maintain certification, pharmacies must:

### 1 - Designate

#### Designate an Authorized Representative to:

- Carry out the certification process
- Oversee implementation and compliance with the REMS on behalf of the pharmacy

### 2 - Review

#### Review the ZILBRYSQ REMS material:

- [Healthcare Provider Safety Brochure](#)

### 3 - Submit

#### Submit the completed Pharmacy Enrollment Form by either:

- Clicking "Start Online Pharmacy Enrollment" below; or
- Scanning and emailing to [ZILBRYSQREMS@ppd.com](mailto:ZILBRYSQREMS@ppd.com); or
- Faxing to 1-877-411-3609

### 4 - Verify

#### Verify prescriber certification online:

- Create an account by clicking "Sign Up / Login"
- Access to secure look-up tool for certified prescribers in the ZILBRYSQ REMS

[Start Online Pharmacy Enrollment](#)

Or - Print and fax, or email to ZILBRYSQ REMS:

 [Pharmacy Enrollment Form](#)

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## Forms and Resources:

### Resources:

- [ZILBRYSQ Healthcare Provider Safety Brochure](#)
- [ZILBRYSQ Patient Guide - English](#)
- [ZILBRYSQ Folleto sobre la seguridad del paciente – Español](#)
- [ZILBRYSQ Patient Safety Card - English](#)
- [ZILBRYSQ Tarjeta de seguridad del paciente – Español](#)
- [Medication Guide](#)
- [Prescribing Information](#)
- [List of Certified Pharmacies](#)

### Forms:

- [ZILBRYSQ Prescriber Enrollment Form](#)
- [ZILBRYSQ Pharmacy Enrollment Form](#)

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# 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?

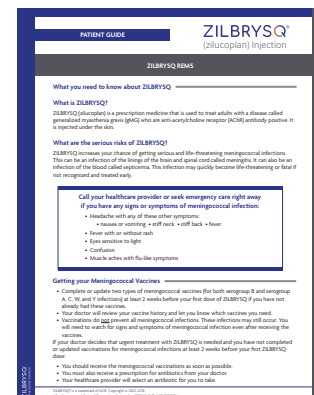
Prescribers must be certified in the ZILBRYSQ REMS before they are eligible to prescribe ZILBRYSQ.

## 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.

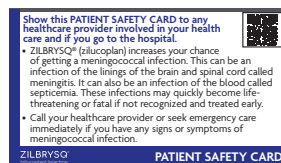
## Before initiating a patient's ZILBRYSQ treatment

- 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:
    - o The risk of meningococcal infections
    - o The need for meningococcal vaccination
    - o 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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(zilucoplan) Injection

## 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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(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

**ZILBRYSQ REMS****What you need to know about ZILBRYSQ****What is ZILBRYSQ?**

ZILBRYSQ (zilucoplan) is a prescription medicine that is used to treat adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. It is injected under the skin.

**What are the serious risks of ZILBRYSQ?**

ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. This infection may quickly become life-threatening or fatal if not recognized and treated early.

**Call your healthcare provider or seek emergency care right away if you have any signs or symptoms of meningococcal infection:**

- Headache with any of these other symptoms:
  - nausea or vomiting
  - stiff neck
  - stiff back
  - fever
- Fever with or without rash
- Eyes sensitive to light
- Confusion
- Muscle aches with flu-like symptoms

**Getting your Meningococcal Vaccines**

- Complete or update two types of meningococcal vaccines (for both serogroup B and serogroup A, C, W, and Y infections) at least 2 weeks before your first dose of ZILBRYSQ if you have not already had these vaccines.
- Your doctor will review your vaccine history and let you know which vaccines you need.
- Vaccinations do not prevent all meningococcal infections. These infections may still occur. You will need to watch for signs and symptoms of meningococcal infection even after receiving the vaccines.

If your doctor decides that urgent treatment with ZILBRYSQ is needed and you have not completed or updated vaccinations for meningococcal infections at least 2 weeks before your first ZILBRYSQ dose:

- You should receive the meningococcal vaccinations as soon as possible.
- You must also receive a prescription for antibiotics from your doctor.
- Your healthcare provider will select an antibiotic for you to take.

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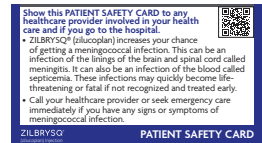
If you have already had both meningococcal vaccines in the past, discuss this with your doctor. You might need to get additional vaccines before you start ZILBRYSQ.

During treatment with ZILBRYSQ, you may also need additional doses of meningococcal vaccines. It is important to discuss this with your doctor to ensure that your vaccination status is always up to date throughout treatment with ZILBRYSQ.

## Patient Safety Card

Your doctor will give you a **Patient Safety Card**.

- The card includes important information about your medical treatment.
- Keep this card with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ.



Show the **Patient Safety Card** to any healthcare provider you go to for treatment.

- The card lets them know about your ZILBRYSQ treatment.
- It will help them diagnose and treat possible meningococcal infection promptly.

Call your doctor or seek emergency care right away for any symptoms of meningococcal infection.

## What is the ZILBRYSQ REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. When there is a REMS, drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks.

ZILBRYSQ has a REMS because it increases your chance of getting a meningococcal infection. This infection can quickly become life-threatening or fatal if not recognized and treated early.

## How will I get ZILBRYSQ?

Only certain pharmacies can fill your ZILBRYSQ prescription. The pharmacies that are part of the ZILBRYSQ REMS will fill your prescription and ship it to you.

If you have questions about the ZILBRYSQ REMS, you can call the REMS or visit the REMS website.

Call: 1-877-414-8353 Monday through Friday, 9:00 AM – 5:00 PM Eastern Time

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

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.

## ZILBRYSQ REMS

## Lo que necesita saber sobre ZILBRYSQ

## ¿Qué es ZILBRYSQ?

ZILBRYSQ (zilucoplan) es un medicamento de venta con receta que se utiliza para tratar a adultos con una enfermedad llamada miastenia gravis generalizada (MMG) que son positivos para anticuerpos antirreceptor de acetilcolina (AChR). Se inyecta bajo la piel.

## ¿Cuáles son los riesgos serios de ZILBRYSQ?

ZILBRYSQ aumenta sus posibilidades de contraer infecciones meningocócicas serias y potencialmente mortales. Esta puede ser una infección del revestimiento del cerebro y la médula espinal llamada meningitis. Puede ser también una infección de la sangre llamada septicemia. Esta infección puede poner en peligro la vida rápidamente o ser mortal si no se identifica y trata a tiempo.

**Llame a su proveedor de atención médica o busque atención médica de emergencia de inmediato si tiene algún signo o síntoma de infección meningocócica:**

- Dolor de cabeza con cualquiera de estos otros síntomas:
  - náuseas o vómitos • rigidez en el cuello • rigidez de la espalda • fiebre
- Fiebre con o sin erupción
- Sensibilidad de los ojos a la luz
- Confusión
- Dolores musculares con síntomas de tipo gripal

## Vacunarse contra el meningococo

- Complete o actualice dos tipos de vacunas meningocócicas (tanto para infecciones del serogrupo B como para el serogrupo A, C, W e Y) al menos 2 semanas antes de su primera dosis de ZILBRYSQ si aún no ha recibido estas vacunas.
- Su médico revisará su historial de vacunas y le informará las vacunas que necesita.
- Las vacunas no previenen todas las infecciones meningocócicas. Aún pueden ocurrir estas infecciones. Deberá estar atento a los signos y síntomas de la infección meningocócica incluso después de recibir las vacunas.

Si su médico decide que es necesario un tratamiento urgente con ZILBRYSQ y usted no ha completado o actualizado sus vacunas contra las infecciones meningocócicas al menos 2 semanas antes de su primera dosis de ZILBRYSQ:

- Debe recibir las vacunas meningocócicas lo antes posible.
- También debe recibir de su médico una receta médica de antibióticos.
- Su proveedor de atención médica seleccionará un antibiótico para que tome.

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Si ya recibió ambas vacunas meningocócicas, coméntelo con su médico. Es posible que necesite recibir vacunas adicionales antes de iniciar ZILBRYSQ.

Durante el tratamiento con ZILBRYSQ, también es posible que necesite dosis adicionales de vacunas meningocócicas. Es importante que comente esto con su médico para asegurarse de que su estado de vacunación esté siempre al día durante todo el tratamiento con ZILBRYSQ.

## Tarjeta de seguridad del paciente

Su médico le entregará una **Tarjeta de Seguridad del Paciente**.

- La tarjeta incluye información importante sobre su tratamiento médico.
- Mantenga esta tarjeta con usted en todo momento durante el tratamiento y durante 2 meses después de la última dosis de ZILBRYSQ. El riesgo de infección meningocócica puede continuar durante varias semanas después de la última dosis de ZILBRYSQ.



Muestre la **tarjeta de seguridad del paciente** a cualquier proveedor de atención médica al que acuda para recibir tratamiento.

- La tarjeta les informa sobre su tratamiento con ZILBRYSQ.
- Les ayudará a diagnosticar y tratar rápidamente una posible infección meningocócica.

Llame a su médico o busque atención médica de emergencia de inmediato ante cualquier síntoma de infección meningocócica.

## ¿Qué es ZILBRYSQ REMS?

Una estrategia de evaluación y mitigación de riesgos (*Risk Evaluation and Mitigation Strategy*, REMS) es un programa de seguridad de los medicamentos que la Administración de Alimentos y Medicamentos de los EE.UU. (*Food and Drug Administration*, FDA) puede exigir para ciertos medicamentos para asegurar que se usen de manera segura. Cuando existe un REMS, las compañías farmacéuticas y los proveedores de atención médica deben tomar medidas adicionales para asegurarse de que los beneficios del uso del medicamento sean mayores a los riesgos.

ZILBRYSQ tiene un REMS porque aumenta sus posibilidades de contraer una infección meningocócica. Esta infección puede convertirse rápidamente en un riesgo para la vida o mortal si no se reconoce y trata a tiempo.

## ¿Cómo obtendré ZILBRYSQ?

Solo determinadas farmacias pueden surtir su receta médica de ZILBRYSQ. Las farmacias que forman parte del ZILBRYSQ REMS surtirán su receta médica y se lo enviarán.

**Si tiene preguntas sobre ZILBRYSQ REMS, puede llamar al REMS o visitar el sitio web de REMS. Llame al: 1-877-414-8353 de lunes a viernes, de 9:00 a.m. a 5:00 p.m., hora del este.**

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

Los casos potenciales de infecciones meningocócicas deben informarse de inmediato a UCB, Inc. al 1-844-599-2273.

Le recomendamos que informe otras reacciones adversas de ZILBRYSQ a UCB Inc. o a la FDA en [www.fda.gov/medwatch](http://www.fda.gov/medwatch) o llame al 1-800-FDA-1088.



Keep this card with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ.

**Show this card to the care provider.**

If you have any signs or symptoms of meningococcal infection, call your healthcare provider right away. If you can't reach your healthcare provider, seek emergency care immediately.

- Call your healthcare provider or seek emergency care immediately if you have any of these signs and symptoms of meningococcal infection:
- Headache with any of these other symptoms:
  - nausea or vomiting – stiff neck – stiff back – fever
  - Fever with or without a rash
  - Eyes sensitive to light
  - Confusion
- Muscle aches with flu-like symptoms

**Carry this Patient Safety Card at all times.**

**Show this PATIENT SAFETY CARD to any healthcare provider involved in your health care and if you go to the hospital.**



- ZILBRYSQ® (zilucoplan) increases your chance of getting a meningococcal infection. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. These infections may quickly become life-threatening or fatal if not recognized and treated early.
- Call your healthcare provider or seek emergency care immediately if you have any signs or symptoms of meningococcal infection.

# ZILBRYSQ<sup>®</sup>

(zilucoplan) Injection

ZILBRYSQ<sup>®</sup> is a trademark of UCB.

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September 2023 US-P-ZL-MG-2200005

## Important Safety Information for Healthcare Providers

This patient has been prescribed ZILBRYSQ (zilucoplan), a complement component 5 (C5) inhibitor that increases the patient's susceptibility to meningococcal infections caused by *Neisseria meningitidis*.

For more information about ZILBRYSQ, please refer to the Prescribing Information.

## PATIENT SAFETY CARD

- Meningococcal infections may rapidly become life-threatening and can be fatal if not diagnosed and treated promptly.
- Evaluate the patient immediately. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection.
- Contact the healthcare provider who prescribed ZILBRYSQ as soon as possible if you suspect a meningococcal infection in this patient. The prescriber is listed on this card.

**Contact the listed ZILBRYSQ prescriber as soon as possible if the patient has signs or symptoms of meningococcal infection.**

For more information about ZILBRYSQ, please refer to the Prescribing Information.

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.

Patient Name \_\_\_\_\_

Prescriber Name \_\_\_\_\_

Prescriber Phone Number \_\_\_\_\_

Emergency Contact Number \_\_\_\_\_

Mantenga esta tarjeta con usted en todo momento durante el tratamiento y durante 2 meses después de su última dosis de ZILBRYSQ. El riesgo de infección meningocócica puede continuar durante varias semanas después de la última dosis de ZILBRYSQ.

**Muestre esta tarjeta al proveedor de atención médica.**

**Si tiene algún signo o síntoma de infección meningocócica, llame de inmediato a su proveedor de atención médica.**  
**Si no puede comunicarse con su proveedor de atención médica, busque atención médica de emergencia de inmediato.**

- Llame a su proveedor de atención médica o busque atención médica de emergencia de inmediato si tiene algún signo o síntoma de infección meningocócica:
- Dolor de cabeza con cualquiera de estos otros síntomas: — náuseas o vómitos — rigidez en el cuello — rigidez de la espalda — fiebre
- Fiebre con o sin erupción
- Sensibilidad de los ojos a la luz
- Confusión
- Dolores musculares con síntomas de tipo gripal

**Lleve esta tarjeta de seguridad del paciente en todo momento.**

**Muestre esta TARJETA DE SEGURIDAD DEL PACIENTE a cualquier proveedor de atención médica y si va al hospital.**



- ZILBRYSQ® (zilucoplan) aumenta sus posibilidades de contraer una infección meningocócica. Esta puede ser una infección del revestimiento del cerebro y la médula espinal llamada meningitis. También puede ser una infección de la sangre llamada septicemia. Estas infecciones pueden volverse rápidamente de riesgo para la vida o mortales si no se reconocen y tratan tiempo.
- Llame a su proveedor de atención médica o busque inmediatamente si tiene algún signo o síntoma de infección.

# ZILBRYSQ®

(zilucoplan) Inyección

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## Información de seguridad importante para proveedores de atención médica

A este paciente se le ha recetado ZILBRYSQ (zilucoplan), un inhibidor del componente 5 (C5) del complemento que aumenta la susceptibilidad del paciente a las infecciones meningocócicas causadas por *Neisseria meningitidis*.

Para obtener más información sobre ZILBRYSQ, consulte la información para prescribir.

## TARJETA DE SEGURIDAD DEL PACIENTE

- Las infecciones meningocócicas pueden convertirse rápidamente en un riesgo para la vida y pueden ser mortales si no se diagnostican y tratan a tiempo.
- Evalúe de inmediato al paciente. Suspenda la administración de ZILBRYSQ en pacientes que estén recibiendo tratamiento por infección meningocócica.
- Comuníquese lo antes posible con el proveedor de atención médica que recetó ZILBRYSQ si sospecha que este paciente tiene una infección meningocócica. El médico que prescribe aparece en esta tarjeta.

**Comuníquese lo antes posible con el médico que recetó ZILBRYSQ indicado si el paciente tiene signos o síntomas de infección meningocócica.**

Para obtener más información sobre ZILBRYSQ, consulte la información de la prescripción.

Los casos potenciales de infecciones meningocócicas deben reportarse de inmediato a UCB, Inc. al 1-844-599-2273

Le recomendamos que informe otras reacciones adversas de ZILBRYSQ a UCB Inc. o a la FDA en [www.fda.gov/medwatch](http://www.fda.gov/medwatch) o llame al 1-800-FDA-1088.

Nombre del paciente \_\_\_\_\_

Nombre del médico que prescribe \_\_\_\_\_

Número de teléfono del médico que prescribe \_\_\_\_\_

Número de contacto de emergencia \_\_\_\_\_

## ZILBRYSQ<sup>®</sup> REMS Certified Pharmacy(-ies)

The list below details the REMS certified pharmacy(-ies) that have access to dispense ZILBRYSQ<sup>®</sup>.

ZILBRYSQ<sup>®</sup> is available through an exclusive specialty pharmacy:

**PANTHERx Rare**

Phone number: 833-418-7760

Fax number: 412-567-6135

24 Summit Park Drive

Pittsburgh, PA 15275

1659762524

Health Care Practitioners: ZILBRYSQ<sup>®</sup> prescriptions are to be dispensed by the REMS certified pharmacy only.

Wholesalers/Distributors and any other entities: Distribution of ZILBRYSQ<sup>®</sup> is to REMS certified pharmacy only.

UCB reserves the right to update and adjust its specialty pharmacy network as needed. Any changes to its network will require the added specialty pharmacy to obtain appropriate REMS certification. This list will be the reference for active REMS certified pharmacy(-ies) that can dispense ZILBRYSQ<sup>®</sup>.

## PRESCRIBER ENROLLMENT FORM

Instructions:

1. Review the ZILBRYSQ Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Guide**, and **Patient Safety Card**.
2. Submit this completed **Prescriber Enrollment Form** to the ZILBRYSQ REMS:
  - Online at [www.ZILBRYSQREMS.com](http://www.ZILBRYSQREMS.com)
  - By scanning and emailing to [ZILBRYSQREMS@ppd.com](mailto:ZILBRYSQREMS@ppd.com)
  - By fax at 1-877-411-3609

**Prescriber Information** (\* fields required)

* First Name:		* Last Name:	
* National Provider Identifier (NPI):		* Email:	
* Credentials: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> APRN <input type="checkbox"/> PA <input type="checkbox"/> Other (please specify):			
* Medical Specialty: <input type="checkbox"/> Neurology <input type="checkbox"/> Other (please specify):			
Clinic / Practice Name:			
* Address Line 1:			
Address Line 2:			
* City:		* State:	* Zip Code:
* Office Phone Number:		* Office Fax Number:	
Alternative Office Phone Number:			

## Prescriber Attestations

By completing, signing, and submitting this form, I acknowledge and agree that:

- I have read and understand the ZILBRYSQ Prescribing Information, **Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card.**
- **Before treatment initiation, I must:**
  - Assess the patient for unresolved meningococcal infection.
  - For patients with unresolved meningococcal infection: Not initiate ZILBRYSQ.
  - Assess the patient's vaccination status for meningococcal serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
  - For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment and must start ZILBRYSQ urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
  - Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide the patient with copies of these materials. Instruct the patient to carry the **Patient Safety Card** at all times and for 2 months after their last ZILBRYSQ dose.
- **During treatment, I must:**
  - Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately, if infection is suspected.
  - For patients who are being treated for meningococcal infections: Withhold administration of ZILBRYSQ.
  - Revaccinate patients according to the current Advisory Committee on Immunization Practices (ACIP) recommendations on meningococcal vaccinations for patients receiving a complement inhibitor.
- **At all times, I must:**
  - Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. at 1-844-599-2273.
- I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe ZILBRYSQ.
- I understand that ZILBRYSQ REMS and its agents or contractors may contact me to support the administration of the REMS.

\*Prescriber's Signature:

\*Date (MM/DD/YYYY):

## PHARMACY ENROLLMENT FORM

**Instructions:**

1. Designate an Authorized Representative to complete training and to commit to training all staff who will be involved in dispensing ZILBRYSQ.
2. Review the **Healthcare Provider Safety Brochure**.
3. Submit this completed **Pharmacy Enrollment Form** to the ZILBRYSQ REMS:

- Online at [www.ZILBRYSQREMS.com](http://www.ZILBRYSQREMS.com)
- By scanning and emailing to [ZILBRYSQREMS@ppd.com](mailto:ZILBRYSQREMS@ppd.com)
- By fax at 1-877-411-3609

**REMS Pharmacy Information** (\* fields required)

- Initial pharmacy enrollment
- Change of information for enrolled pharmacy
- Change of authorized representative

Authorized Representative Information		
* First Name:	* Last Name:	
*Title/Position: <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other (please specify):		
*Authorized Representative National Provider Identifier (NPI):		
*Email:	*Preferred Method of Communication: <input type="checkbox"/> Email <input type="checkbox"/> Phone	
Pharmacy Information		
*Pharmacy Name:		
* Address Line 1:		
Address Line 2:		
* City:	* State:	* Zip Code:
* Phone Number:	* Fax Number:	
*Pharmacy National Provider Identifier (NPI):		



## Authorized Representative Attestations

### As the Authorized Representative, I must:

- Review the **Healthcare Provider Safety Brochure**.
- Train all relevant staff who will be involved in dispensing ZILBRYSQ using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to verify the prescriber is certified and document the findings.
- Establish processes and procedures to contact 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: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis if needed by contacting the prescriber before dispensing prescriptions up to 6 months after the first dose and document the findings.

### Before dispensing the first dose, all pharmacy staff must:

- 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.

### For up to 6 months after dispensing the first dose, all pharmacy staff must:

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: 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, all pharmacy staff must:

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

### At all times, my pharmacy must:

- Report adverse events suggestive of meningococcal infection to UCB, Inc. by email at ds.usa@ucb.com.
- Not distribute, transfer, loan, or sell ZILBRYSQ, except to certified pharmacies.
- Maintain records of staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and are 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 are being followed.

### To maintain certification to dispense, any new Authorized Representative must:

- Enroll in the REMS by completing and submitting this **Pharmacy Enrollment Form** to the REMS.

\*Authorized Representative Signature:

\*Date (MM/DD/YYYY):

## Contact Us:

If you have any questions or require additional information, please contact us using one of the methods listed below. The ZILBRYSQ REMS Call Center is available Monday through Friday from 9:00 am - 5:00 pm ET.

**Phone:**

**1-877-414-8353**

**Fax:**

**1-877-411-3609**

**Email Address:**

**ZILBRYSQREMS@ppd.com**

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