CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218037Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
VOYDEYA™ (danicopan) REMS

I. Administrative Information

Risk: Serious infections caused by encapsulated bacteria
Application Number: NDA 218037
Application Holder: Alexion Pharmaceuticals, Inc.
Initial REMS approval: 03/2024

II. REMS Goal

The goal of the VOYDEYA REMS is to mitigate the risk of serious infections caused by encapsulated bacteria.

1. Patients are vaccinated against infections caused by encapsulated bacteria (*Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae*) prior to starting therapy according to 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 serious encapsulated bacterial infections and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.

III. REMS Requirements

Alexion Pharmaceuticals, Inc. must ensure that healthcare providers, patients, and pharmacies comply with the following requirements:

1. Healthcare providers who prescribe VOYDEYA must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide. 3. Enroll by completing and submitting the Prescriber Enrollment Form to the REMS.
Before treatment initiation	4. Assess the patient for unresolved serious infections caused by encapsulated bacteria. 5. For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate VOYDEYA. 6. Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae* and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations. 7. For patients who are not up to date with meningococcal and pneumococcal vaccines at least 2 weeks prior to initiation of treatment and who must start VOYDEYA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.

	8. Counsel the patient using the Patient Safety Card and Patient Guide. Provide a copy of the materials to the patient. 9. Counsel the patient on the need to carry the Patient Safety Card at all times during treatment and for 1 week following the last dose of VOYDEYA.
During treatment	10. Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately, if infection is suspected. 11. Vaccinate patients as needed according to the current ACIP recommendations.
At all times	12. Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals, Inc.

2. Patients who are prescribed VOYDEYA:

Before treatment initiation	1. Get vaccinated as directed by your prescriber against the following encapsulated bacteria: *Neisseria meningitidis* serogroups A, C, W, Y and B; and *Streptococcus pneumoniae*. 2. Take antibiotics as directed by your prescriber if you have to start VOYDEYA right away. 3. Receive counseling from your prescriber using the Patient Safety Card and Patient Guide. 4. Get the Patient Safety Card and Patient Guide from your prescriber.
During treatment	5. Get additional vaccines as directed by your prescriber.
At all times during treatment and for 1 week after the last dose	6. Inform your prescriber or get emergency medical care right away if any of the following occur: fever with or without chills; fever and a rash; fever with chest pain and cough; fever with breathlessness/fast breathing; fever with high heart rate; headache with nausea or vomiting; headache and a fever; headache with a stiff neck or stiff back; confusion; body aches with flu-like symptoms; clammy skin; eyes sensitive to light. 7. Have the Patient Safety Card with you.

3. Outpatient pharmacies that dispense VOYDEYA must:

To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll in the REMS by completing and submitting the Outpatient Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing VOYDEYA using the Healthcare Provider Safety Brochure. 5. Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings. 6. For patients who are not up to date with meningococcal and pneumococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date

	meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.
Before dispensing, first dose	7. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 8. Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, for up to 6 months after the first dose	9. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 10. For patients who are not initially up to date with meningococcal and pneumococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, 6 months after the first dose and thereafter	11. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
To maintain certification to dispense	12. If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the Outpatient Pharmacy Enrollment Form to the REMS.
At all times	13. Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc. 14. Not distribute, transfer, loan, or sell VOYDEYA, except to other certified pharmacies. 15. Maintain records of staff's completion of REMS training. 16. Maintain records that all processes and procedures are in place and are being followed. 17. Comply with audits carried out by Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.
4. Inpatient pharmacies that dispense VOYDEYA must:	
To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll in the REMS by completing and submitting the Inpatient Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing VOYDEYA using the Healthcare Provider Safety Brochure. 5. Establish processes and procedures to verify if the patient is initiating or continuing treatment. 6. For patients initiating treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory

	Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.
Before dispensing, first dose	7. Verify if the patient is initiating or continuing treatment through the processes and procedures established as a requirement of the REMS. 8. For patients initiating treatment: Obtain authorization to dispense by contacting the REMS to verify the prescriber is certified. 9. For patients initiating treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.
At discharge	10. Dispense no more than a 30 days' supply.
To maintain certification to dispense	11. If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the Inpatient Pharmacy Enrollment Form to the REMS.
At all times	12. Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc. 13. Not distribute, transfer, loan, or sell VOYDEYA, except to certified pharmacies. 14. Maintain records of staff's completion of REMS training. 15. Maintain records that all processes and procedures are in place and are being followed. 16. Comply with audits carried out by Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

Alexion Pharmaceuticals, Inc. must provide training to healthcare providers who prescribe VOYDEYA.
The training includes the following educational materials: Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide. The training must be available online and in hardcopy format via fax.

Alexion Pharmaceuticals, Inc. must provide training to pharmacies that dispense VOYDEYA.
The training includes the following educational material: Healthcare Provider Safety Brochure. The training must be available online and in hardcopy format via fax.

To support REMS operations, Alexion Pharmaceuticals, Inc. must:

1. Distribute VOYDEYA only to certified pharmacies.
2. Establish and maintain the REMS Websites, www.AlexionREMS.com and www.VoydeyaREMS.com. The REMS Websites must include the capability to complete the prescriber certification and enrollment online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Websites. The REMS Websites must not link back to the promotional product website(s).
3. Make the REMS Websites fully operational and all REMS materials available through the REMS Websites and REMS Call Center by the date VOYDEYA is first commercially distributed.
4. Establish and maintain a REMS Call Center for REMS participants at 1-888-765-4747.

5. Establish and maintain a validated, secure database of all certified prescribers and pharmacies in the VOYDEYA REMS, and patient-specific information on vaccination and antibacterial drug prophylaxis.
6. Ensure that prescribers are able to enroll in the REMS by fax, email, and online.
7. Ensure that pharmacies are able to enroll in the REMS by fax and email.
8. Ensure that prescribers and pharmacies are able to report vaccination and antibacterial drug prophylaxis information online and by fax.
9. Ensure that pharmacies are able to obtain authorization to dispense by phone or online.
10. Ensure that prescribers and pharmacies are able to report adverse events suggestive of serious bacterial infections by phone.
11. Ensure that once a report suggestive of serious bacterial infection is received, Alexion Pharmaceuticals, Inc. will follow up with the healthcare providers to obtain all required data. This requirement does not affect Alexion Pharmaceuticals, Inc.'s other reporting and follow-up requirements under the FDA regulations.
12. Provide the Prescriber Enrollment Form, Healthcare Provider Safety Brochure, Patient Safety Card, Patient Guide, Medication Guide, and the Prescribing Information to healthcare providers who (1) attempt to prescribe VOYDEYA and are not yet certified or (2) inquire about how to become certified.
13. Provide the Healthcare Provider Safety Brochure and Outpatient Pharmacy Enrollment Form or Inpatient Pharmacy Enrollment Form to pharmacies who (1) attempt to order/dispense VOYDEYA and are not yet certified or (2) inquire about how to become certified.
14. Notify prescribers and pharmacies within 2 business days after they become certified in the REMS.
15. Provide certified prescribers access to a database of certified pharmacies and patient-specific information on vaccination and antibacterial drug prophylaxis.
16. Provide certified pharmacies access to a database of certified prescribers and patient-specific information on vaccination and antibacterial drug prophylaxis.

To ensure REMS participants' compliance with the REMS, Alexion Pharmaceuticals, Inc. must:

17. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: VOYDEYA distribution and dispensing; certification of prescribers and pharmacies; patient-specific information on vaccination and antibacterial drug prophylaxis; and audits of REMS participants. These records must be readily available for FDA inspections.
18. Verify annually that the designated Authorized Representative's name and contact information correspond to those of the current designated Authorized Representative for the pharmacy. If different, the pharmacy must be required to re-certify with a new Authorized Representative.
19. Establish and maintain a plan for addressing noncompliance with REMS requirements.
20. Monitor prescribers and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.
21. Audit certified outpatient and inpatient pharmacies no later than 180 calendar days after they receive their first shipment, and a representative sample of certified pharmacies annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and comply with the REMS requirements.
22. Take reasonable steps to improve operations of and compliance with the requirements of the VOYDEYA REMS based on monitoring and evaluation of the VOYDEYA REMS.

IV. REMS Assessment Timetable

Alexion Pharmaceuticals, Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Alexion Pharmaceuticals, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the VOYDEYA REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Pharmacy:

2. Outpatient Pharmacy Enrollment Form
3. Inpatient Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

4. Healthcare Provider Safety Brochure

Patient:

5. Patient Safety Card
6. Patient Guide

Pharmacy:

7. Healthcare Provider Safety Brochure

Other Materials

8. REMS Websites (www.AlexionREMS.com and www.VoydeyaREMS.com)

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use:
    - Healthcare providers who prescribe VOYDEYA are specially certified under 505-1(f)(3)(A)
    - Pharmacies that dispense VOYDEYA are specially certified under 505-1(f)(3)(B)
    - VOYDEYA is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for Submission of Assessments

Voydeya™ (danicopan)

PRESCRIBER ENROLLMENT FORM

Instructions

To become certified in the VOYDEYA REMS and prescribe VOYDEYA™:

1. Review the VOYDEYA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. Enroll in the REMS by completing and submitting this form:
   - online at www.VoydeyaREMS.com
   - by fax at 1-866-750-0785
   - by scanning and emailing to Voydeya@AlexionREMS.com

Prescriber Information (*Indicates Required Field)

*First Name:	MI:	*Last Name:
*National Provider Identifier (NPI):		*Email:
*Clinic/Practice Name:		
*Address Line 1:		
Address Line 2:		
*City:	*State:	*ZIP Code:
*Office Phone Number:	Extension:	Office Fax Number:

*Credentials: ☐ MD ☐ DO ☐ APRN[1] ☐ PA ☐ PharmD

*Medical Specialty (please select one):

☐ Hematology/Oncology ☐ Immunology ☐ Internal medicine ☐ Nephrology ☐ Neurology ☐ Rheumatology

☐ Other (please specify):_____

[1]Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM).

Prescriber Designee Information

Please Note: A prescriber designee is an office contact or administrative support staff for the prescriber's office, who will be able to enter patient vaccination and antibacterial drug prophylaxis information on the prescriber's behalf.

First Name:	Last Name:
Phone:	Email:

Prescriber Agreement

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

- I have read and understand the VOYDEYA Prescribing Information (PI), **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.

Reference ID: 5356289

Before treatment initiation, I must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate VOYDEYA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y and B; and *Streptococcus pneumoniae* and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal and pneumococcal vaccines at least two weeks prior to initiation of treatment and who must start VOYDEYA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 1 week following the last dose of VOYDEYA.

During treatment, I must:

- Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately, if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations.

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals, Inc at 1-844-259-6783.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe VOYDEYA.

I understand that VOYDEYA REMS and its agents or contractors may contact me to support the administration of the REMS.

I understand that Alexion or its agents or contractors may use and disclose my information in accordance with the Alexion Privacy Notice, available at www.alexion.com/legal#privacy, including to support the administration of the VOYDEYA REMS.

***Prescriber's Signature:** _____

***Date (MM/DD/YYYY):** _____

Voydeya™ (danicopan)

Reference ID: 5356289

Voydeya™ (danicopan)

OUTPATIENT PHARMACY ENROLLMENT FORM

Instructions

To become certified in the VOYDEYA REMS and dispense VOYDEYA™, the **outpatient pharmacy** must designate an Authorized Representative to:

1. Review the **Healthcare Provider Safety Brochure**.
2. Enroll in the REMS by completing and submitting this form:
   - by fax at 1-866-750-0785
   - by scanning and emailing to Voydeya@AlexionREMS.com

Authorized Representative Information (*Indicates Required Field)

*First Name:	MI:	*Last Name:
*Office Phone Number:	*Office Fax Number:	*Email:
*Title/Position:		

Outpatient Pharmacy Information (*Indicates Required Field)

*Outpatient Pharmacy Name:

*National Provider Identifier (NPI):

*Type of Pharmacy (please select one):

☐ Specialty Pharmacy ☐ Other (please specify) _____

*Address Line 1:

Address Line 2:

*City:	*State:	*ZIP Code:
*Pharmacy Phone Number:	*Pharmacy Fax Number:	

Authorized Representative Responsibilities

As the outpatient pharmacy Authorized Representative, to become certified to dispense, I must:

- Review the **Healthcare Provider Safety Brochure**.
- Train all relevant staff involved in dispensing VOYDEYA using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines 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 and pneumococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Reference ID: 5356289

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

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, for up to 6 months after the first dose, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal and pneumococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

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

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

At all times, all outpatient pharmacy staff must:

- Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc.
- Not distribute, transfer, loan, or sell VOYDEYA, except to other 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 Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

I understand that if this pharmacy does not maintain compliance with the requirements of the REMS, the pharmacy will no longer be able to dispense VOYDEYA.

I understand that the VOYDEYA REMS and its agents or contractors may contact me to support the administration of the REMS.

I understand that Alexion or its agents or contractors may use and disclose my information in accordance with the Alexion Privacy Notice, available at www.alexion.com/legal#privacy, including to support the administration of the VOYDEYA REMS.

***Authorized Representative Signature:** _____

***Date (MM/DD/YYYY):** _____

Voydeya™ (danicopan)

Reference ID: 5356289

Voydeya™ (danicopan)

INPATIENT PHARMACY ENROLLMENT FORM

Instructions

To become certified in the VOYDEYA REMS and dispense VOYDEYA™, the **inpatient pharmacy** must designate an Authorized Representative to:

1. Review the **Healthcare Provider Safety Brochure**.
2. Enroll in the REMS by completing and submitting this form:
   - by fax at 1-866-750-0785
   - by scanning and emailing to Voydeya@AlexionREMS.com

Authorized Representative Information (*Indicates Required Field)

*First Name:	MI:	*Last Name:
*Office Phone Number:	*Office Fax Number:	*Email:
*Title/Position:		

Inpatient Pharmacy Information (*Indicates Required Field)

*Inpatient Pharmacy Name:

*National Provider Identifier (NPI):

*Type of Pharmacy (please select one):

☐ Hospital ☐ Hospice ☐ Rehabilitation Facility

*Address Line 1:

Address Line 2:

*City:	*State:	*ZIP Code:
*Pharmacy Phone Number:	*Pharmacy Fax Number:	

Authorized Representative Responsibilities

As the inpatient pharmacy Authorized Representative, to become certified to dispense, I must:

- Review the **Healthcare Provider Safety Brochure**.
- Train all relevant staff involved in dispensing VOYDEYA using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to verify if the patient is initiating or continuing treatment.
- For patients initiating treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

Reference ID: 5356289

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

- Verify if the patient is initiating or continuing treatment through the processes and procedures established as a requirement of the REMS.
- For patients initiating treatment: Obtain authorization to dispense by contacting the REMS to verify the prescriber is certified.
- For patients initiating treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

At discharge, all inpatient pharmacy staff must:

- Dispense no more than a 30 days' supply.

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

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

At all times, all inpatient pharmacy staff must:

- Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc.
- Not distribute, transfer, loan, or sell VOYDEYA, 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 Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, Inc., to ensure that all REMS processes and procedures are in place and are being followed.

I understand that if this pharmacy does not maintain compliance with the requirements of the REMS, the pharmacy will no longer be able to dispense VOYDEYA.

I understand that the VOYDEYA REMS and its agents or contractors may contact me to support the administration of the REMS.

I understand that Alexion or its agents or contractors may use and disclose my information in accordance with the Alexion Privacy Notice, available at www.alexion.com/legal#privacy, including to support the administration of the VOYDEYA REMS.

***Authorized Representative Signature:** _____

***Date (MM/DD/YYYY):** _____

Voydeya™ (danicopan)

Reference ID: 5356289

Voydeya™
(danicopan)

HEALTHCARE PROVIDER SAFETY BROCHURE

This brochure provides information for healthcare providers who prescribe or dispense VOYDEYA™. It describes:

- What is VOYDEYA?
- What is the VOYDEYA REMS?
- Prescriber Requirements
- Outpatient Pharmacy Requirements
- Inpatient Pharmacy Requirements
- VOYDEYA REMS Resources
- Adverse Event Reporting

Reference ID: 5356289

What is VOYDEYA?

VOYDEYA is indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

Limitations of Use
VOYDEYA has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

Risk of serious infections caused by encapsulated bacteria:

- VOYDEYA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening or fatal infections caused by encapsulated bacteria including *Neisseria meningitidis* (caused by any serogroup, including non-groupable strains), *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B.
- Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors.
- The initiation of VOYDEYA treatment is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.
- Complete or update vaccination against encapsulated bacteria (*Neisseria meningitidis* serogroups A, C, W, Y, and B and *Streptococcus pneumoniae*) at least 2 weeks prior to administration of the first dose of VOYDEYA, according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.
- If urgent VOYDEYA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible.
- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of serious infections and evaluate patients immediately if an infection is suspected. Promptly treat known infections.
- Serious infections may become rapidly life-threatening or fatal if not recognized and treated early.
- Inform patients of these signs and symptoms of serious infections and instruct patients to seek immediate medical care if these signs and symptoms occur.
- Consider interruption of VOYDEYA in patients who are undergoing treatment for serious infections.

What is the VOYDEYA REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks.

Because of the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through the VOYDEYA REMS, a restricted distribution program.

Prescriber Requirements

What do prescribers need to do to prescribe VOYDEYA?

Healthcare providers who prescribe VOYDEYA must be certified in the REMS to prescribe.
To become certified to prescribe VOYDEYA, prescribers must:

1) Review the VOYDEYA Prescribing Information
2) Review the **Healthcare Provider Safety Brochure** (this document), **Patient Safety Card**, and **Patient Guide**
3) Complete and submit the **Prescriber Enrollment Form**
   - online at www.VoydeyaREMS.com
   - by fax at 1-866-750-0785
   - by scanning and emailing to Voydeya@AlexionREMS.com

All REMS materials are available on the **REMS Website** (www.VoydeyaREMS.com) or by calling the REMS at 1-888-765-4747.

Before initiating a patient's VOYDEYA treatment prescribers must:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria and not initiate VOYDEYA therapy in any patient with these infections.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae* and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal and pneumococcal vaccines at least 2 weeks prior to initiation of treatment and who must start VOYDEYA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
    - The **Patient Guide** provides information for your patients about the risk of serious infections. Inform patients of the following:
        - The need to complete or update their vaccinations against encapsulated bacteria at least 2 weeks prior to receiving the first dose of VOYDEYA or receive antibacterial drug prophylaxis if VOYDEYA treatment must be initiated immediately and they have not previously been vaccinated.
        - Additional vaccines may be necessary during treatment with VOYDEYA.
        - Vaccines do not prevent all serious infections caused by encapsulated bacteria.
    - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the following signs and symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation:
        - Fever with or without chills
        - Fever and a rash
        - Fever with chest pain and cough
        - Fever with breathlessness/fast breathing
        - Fever with high heart rate
        - Headache with nausea or vomiting
        - Headache and a fever
        - Headache with a stiff neck or stiff back
        - Confusion
        - Body aches with flu-like symptoms
        - Clammy skin
        - Eyes sensitive to light
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 1 week following the last dose of VOYDEYA. Instruct your patient to show the card to any healthcare provider involved in their care.

During VOYDEYA treatment, prescribers must:

- Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to current ACIP recommendations.

At all times, prescribers must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals Inc. at 1-844-259-6783.
- Comply with the VOYDEYA REMS requirements to maintain certification to prescribe.

Certified pharmacies must assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed. If you have not provided information already, you will receive a call from the pharmacy to collect information confirming that the patient has received the appropriate vaccinations or antibacterial drug prophylaxis.

Outpatient Pharmacy Requirements

What do outpatient pharmacies need to do when dispensing VOYDEYA?

VOYDEYA may only be dispensed by outpatient pharmacies that are certified to dispense.

To become certified to dispense VOYDEYA, the outpatient pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

The Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- Complete and submit the **Outpatient Pharmacy Enrollment Form**:
  - By fax at 1-866-750-0785
  - By scanning and emailing to Voydeya@AlexionREMS.com
- Call the VOYDEYA REMS at 1-888-765-4747 to obtain the **Outpatient Pharmacy Enrollment Form**.

By completing and submitting the Outpatient Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing VOYDEYA using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines 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 and pneumococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

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

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, 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 outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal and pneumococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

After the first 6 months of dispensing, all outpatient pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

At all times, the outpatient pharmacy must:

- Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc.
- Not distribute, transfer, loan, or sell VOYDEYA, except to other 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 Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, 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 the **Outpatient Pharmacy Enrollment Form** to the REMS.

Inpatient Pharmacy Requirements

What do inpatient pharmacies need to do when dispensing VOYDEYA?

VOYDEYA may only be dispensed by inpatient pharmacies that are certified to dispense.

To become certified to dispense VOYDEYA, the inpatient pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

The Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- Complete and submit the **Inpatient Pharmacy Enrollment Form**:
  - By fax at 1-866-750-0785
  - By scanning and emailing to Voydeya@AlexionREMS.com
- Call the VOYDEYA REMS at 1-888-765-4747 to obtain the **Inpatient Pharmacy Enrollment Form**.

By completing and submitting the Inpatient Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing VOYDEYA using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to verify if the patient is initiating or continuing treatment.
- For patients initiating treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

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

- Verify if the patient is initiating or continuing treatment through the processes and procedures established as a requirement of the REMS.
- For patients initiating treatment: Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients initiating treatment: Assess the patient's vaccination status for up to date meningococcal and pneumococcal vaccines according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

At discharge, all inpatient pharmacy staff must:

- Dispense no more than a 30 days' supply.

At all times, the inpatient pharmacy must:

- Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc.
- Not distribute, transfer, loan, or sell VOYDEYA, except to other 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 Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, 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 the **Inpatient Pharmacy Enrollment Form** to the REMS.

VOYDEYA REMS Resources

Visit www.VoydeyaREMS.com or call 1-888-765-4747 to learn more about the VOYDEYA REMS.

Adverse Event Reporting

Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, immediately to Alexion Pharmaceuticals Inc. at 1-844-259-6783.

You are encouraged to report other adverse reactions of VOYDEYA to Alexion Pharmaceuticals Inc. at 1-844-259-6783 or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This brochure does not provide all risk information for VOYDEYA. Please see the Prescribing Information for VOYDEYA, including BOXED WARNING for serious infections caused by encapsulated bacteria for more detailed safety information.

Voydeya™ (danicopan)

PATIENT SAFETY CARD

Important Safety Information for Patients Taking VOYDEYA™ (danicopan)

VOYDEYA increases your chance of getting serious infections caused by encapsulated bacteria. These serious infections may quickly become life-threatening and cause death if not recognized and treated early. If you experience any of the following signs and symptoms of a serious infection, you should call your healthcare provider or get emergency medical care right away:

- fever with or without chills
- fever and a rash
- fever with chest pain and cough
- fever with breathlessness/fast breathing
- fever with high heart rate
- headache with nausea or vomiting
- headache and a fever
- headache with a stiff neck or stiff back
- confusion
- body aches with flu-like symptoms
- clammy skin
- eyes sensitive to light

Get emergency medical care right away if you have any of these signs or symptoms and show this card to any healthcare provider who treats you.

Keep this card with you at all times during your treatment and for 1 week after your last VOYDEYA dose. Your risk of serious infections may continue for a few days after your last dose of VOYDEYA.

Reference ID: 5356289

PATIENT SAFETY CARD

Information for the Treating Physician

Serious Infections Caused by Encapsulated Bacteria

This patient has been prescribed VOYDEYA (danicopan) therapy, which increases the patient's susceptibility to serious infections caused by encapsulated bacteria, including *Neisseria meningitidis* (caused by any serogroup, including non-groupable strains), *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B.

- Serious infections may rapidly become life-threatening or fatal if not recognized and treated early.
- **Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Promptly treat known infections.**
- Contact the healthcare provider who prescribed VOYDEYA (listed below) as soon as possible if the patient has signs or symptoms of serious infection.

For more information about VOYDEYA, please refer to the Prescribing Information. Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals Inc. at 1-844-259-6783.

Patient Name_____

Prescriber Name_____

Prescriber Phone Number_____

Phone: 1-888-765-4747 | www.VoydeyaREMS.com | Fax: 1-866-750-0785

Voydeya™ (danicopan)

Voydeya™
(danicopan)

What You Need to Know About VOYDEYA™

PATIENT GUIDE

Phone: 1-888-765-4747
www.VoydeyaREMS.com
Fax: 1-866-750-0785

Reference ID: 5356289

What is VOYDEYA?

VOYDEYA (danicopan) is a prescription medicine used along with ravulizumab or eculizumab to treat breakdown of red blood cells that takes place outside of blood vessels (extravascular hemolysis), in adults with paroxysmal nocturnal hemoglobinuria (PNH).

What are the serious risks of VOYDEYA?

VOYDEYA is a medicine that may lower the ability of your immune system to fight infections.

VOYDEYA increases your chance of getting serious infections caused by encapsulated bacteria, including *Neisseria meningitis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B. These serious infections may quickly become life-threatening and cause death if not recognized and treated early.

Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious infection:

- Fever with or without chills
- Fever and a rash
- Fever with chest pain and cough
- Fever with breathlessness/fast breathing
- Fever with high heart rate
- Headache with nausea or vomiting
- Headache and a fever
- Headache with a stiff neck or stiff back
- Confusion
- Body aches with flu-like symptoms
- Clammy skin
- Eyes sensitive to light

Getting Your Vaccines

- You must complete or be up to date with the vaccines against *Neisseria meningitidis* and *Streptococcus pneumoniae* at least 2 weeks before your first dose of VOYDEYA.
- If you have not completed your vaccinations and VOYDEYA must be started right away, you should receive the required vaccinations as soon as possible.
- If you have not been vaccinated at least 2 weeks before your first VOYDEYA dose, and treatment with VOYDEYA must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
- If you have been vaccinated against these bacteria in the past, you might need additional vaccinations before starting VOYDEYA. Your healthcare provider will decide if you need additional vaccinations.
- Vaccines do not prevent all infections caused by encapsulated bacteria.
- Keep your vaccination records in a safe place and notify your healthcare provider that you have been vaccinated.

Your healthcare provider and the certified pharmacy may contact you to verify your vaccination records before your medicine is provided to you.

Patient Safety Card

You will receive a **Patient Safety Card** from your healthcare provider about the risk of serious infections.

- Carry this card with you at all times during treatment and for 1 week after your last VOYDEYA dose. Your risk of serious infections may continue for a few days after your last dose of VOYDEYA.
- **Show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.**

What is the VOYDEYA 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, healthcare providers, and pharmacies must take extra steps to make sure the benefits of using the drug are greater than the risks.

VOYDEYA has a REMS because it can increase your chance of getting serious infections caused by encapsulated bacteria. Serious infections may quickly become life-threatening and cause death if not recognized and treated early.

ALEXION®
AstraZeneca Rare Disease

Alexion REMS Platform

Risk Evaluation and Mitigation Strategies (REMS) are drug safety programs required by the U.S. Food and Drug Administration (FDA) for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. This page provides links to the REMS Programs for certain Alexion Pharmaceuticals, Inc. products.

ULTOMIRIS® (ravulizumab-cwvz)

Medication Guide

Prescribing Information

ULTOMIRIS AND SOLIRIS REMS

REMS Approval Date: 03/22/2024

Learn More

SOLIRIS® (eculizumab)

Medication Guide

Prescribing Information

ULTOMIRIS AND SOLIRIS REMS

REMS Approval Date: 03/22/2024

Learn More

Voydeya™ (danicopan)

Medication Guide

Prescribing Information

VOYDEYA REMS

REMS Approval Date: 99/99/9999

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AstraZeneca Rare Disease

For additional information or questions, please contact the REMS at
1-888-765-4747
Monday - Friday
8:00 am – 8:00 pm Eastern Time

ALEXION®
AstraZeneca Rare Disease

Alexion REMS Platform

Risk Evaluation and Mitigation Strategies (REMS) are drug safety programs required by the U.S. Food and Drug Administration (FDA) for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. This page provides links to the REMS Programs for certain Alexion Pharmaceuticals, Inc. products.

ULTOMIRIS® (ravulizumab-cwvz)

ULTOMIRIS AND SOLIRIS REMS

REMS Approval Date: 03/22/2024

Medication Guide

Prescribing Information

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Learn More

SOLIRIS® (eculizumab)

ULTOMIRIS AND SOLIRIS REMS

REMS Approval Date: 03/22/2024

Medication Guide

Prescribing Information

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Voydeya™ (danicopan)

VOYDEYA REMS

REMS Approval Date: 99/99/9999

Medication Guide

Prescribing Information

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AstraZeneca Rare Disease

For additional information or questions, please contact the REMS at
1-888-765-4747
Monday - Friday
8:00 am – 8:00 pm Eastern Time

ALEXION®
AstraZeneca Rare Disease

Alexion REMS Platform

Steve Meru

Risk Evaluation and Mitigation Strategies (REMS) are drug safety programs required by the U.S. Food and Drug Administration (FDA) for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. This page provides links to the REMS Programs for certain Alexion Pharmaceuticals, Inc., products.

ULTOMIRIS® (ravulizumab-cwvz)

ULTOMIRIS AND SOLIRIS REMS
REMS Approval Date: 03/22/2024

My Profile
Status: ● CERTIFIED

Medication Guide
Prescribing Information
Continue

SOLIRIS® (eculizumab)

ULTOMIRIS AND SOLIRIS REMS
REMS Approval Date: 03/22/2024

My Profile
Status: ● CERTIFIED

Medication Guide
Prescribing Information
Continue

Voydeya™ (danicopan)

VOYDEYA REMS
REMS Approval Date: 99/99/9999

Medication Guide
Prescribing Information
Quick Enroll

Learn More

ALEXION®
AstraZeneca Rare Disease

For additional information or questions, please contact the REMS at
1-888-765-4747
Monday - Friday
8:00 am – 8:00 pm Eastern Time

Reference ID: 5356289

VOYDEYA™ Risk Evaluation and Mitigation Strategy (REMS)

What is the VOYDEYA REMS?

VOYDEYA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the VOYDEYA REMS, because of the risk of serious infections caused by encapsulated bacteria.

The goal of the VOYDEYA REMS is to mitigate the risk of serious infections caused by encapsulated bacteria.

1. Patients are vaccinated against infections caused by encapsulated bacteria *(Neisseria meningitidis* serogroups A, C, W, Y, and B; and *Streptococcus pneumoniae)* prior to starting therapy according to 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 serious encapsulated bacterial infections and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of serious encapsulated bacterial infections and the need for immediate medical evaluation.

HEALTHCARE PROVIDERS

Prescribers must be certified in the VOYDEYA REMS to prescribe to patients.

Learn More >

OUTPATIENT PHARMACIES

Outpatient pharmacies must be certified in the VOYDEYA REMS to dispense to patients.

Learn More >

INPATIENT PHARMACIES

Inpatient pharmacies must be certified in the VOYDEYA REMS to dispense to patients.

Learn More >

Indications

VOYDEYA is indicated as add-on therapy to ravulizumab or eculizumab for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).

Limitations of Use

VOYDEYA has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

Reporting Adverse Events

Report adverse events suggestive of serious bacterial infections to Alexion Pharmaceuticals, Inc. at 1-844-259-6783. You are encouraged to report other adverse reactions of VOYDEYA to Alexion Pharmaceuticals, Inc. or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Resources for Healthcare Providers

- Healthcare Provider Safety Brochure
- Prescriber Enrollment Form
- Patient Safety Card
- Patient Safety Card - Spanish
- Patient Guide
- Patient Guide - Spanish

Download All Healthcare Provider Resources

Resources for Outpatient Pharmacies

- Healthcare Provider Safety Brochure

Download All Outpatient Pharmacy Resources

Resources for Inpatient Pharmacies

- Healthcare Provider Safety Brochure

Download All Inpatient Pharmacy Resources

Healthcare Providers

Requirements for Healthcare Providers

VOYDEYA™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), because of the risk of serious infections caused by encapsulated bacteria.

Healthcare Providers who prescribe VOYDEYA must be specially certified.

Healthcare Provider Certification

1

Review the following:

- Prescribing Information
- **Healthcare Provider Safety Brochure**
- **Patient Safety Card**
- **Patient Guide**

→

2

Enroll in the VOYDEYA REMS by completing and submitting the **Prescriber Enrollment Form**:

- Online
- Fax
  - Fax the form to VOYDEYA REMS at 1-866-750-0785
- Email
  - Scan and email the form to Voydeya@AlexionREMS.com

Patient Counseling

Prescribers must:

- Counsel the patients using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
  - The **Patient Guide** provides information for your patients about the risk of serious infections. Inform patients of the following:
    - The need to complete or update their vaccinations against encapsulated bacteria at least 2 weeks prior to receiving the first dose of VOYDEYA or receive antibacterial drug prophylaxis if VOYDEYA treatment must be initiated immediately and they have not previously been vaccinated.
    - Additional vaccines may be necessary during treatment with VOYDEYA.
    - Vaccines do not prevent all serious infections caused by encapsulated bacteria.
  - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes signs and symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 1 week following the last dose of VOYDEYA. Instruct your patient to show the card to any healthcare provider involved in their care.

Resources for Healthcare Providers

- Healthcare Provider Safety Brochure
- Prescriber Enrollment Form
- Patient Safety Card
- Patient Safety Card - Spanish
- Patient Guide
- Patient Guide - Spanish

Download All Healthcare Provider Resources

Prescriber Enrollment

VOYDEYA REMS
Prescriber Enrollment Form

Instructions

To become certified in the VOYDEYA REMS and prescribe VOYDEYA™:

1. **Review** the VOYDEYA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. **Enroll** in the REMS by completing and submitting this form below.

(* Indicates Required Field)

Prescriber Information

*National Provider Identifier (NPI)

Continue

Prescriber Enrollment

VOYDEYA REMS
Prescriber Enrollment Form

Instructions

To become certified in the VOYDEYA REMS and prescribe VOYDEYA™:

1. **Review** the VOYDEYA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. **Enroll** in the REMS by completing and submitting this form below.

(* Indicates Required Field)

Prescriber Information

*National Provider Identifier (NPI)
1234567890

*First Name: Steve | MI | *Last Name: Meru | *Email: abc@abc.com

*Clinic/Practice Name: ABC

*Address Line 1: 123 Main Street | Address Line 2

*City: Philadelphia | *State: PA | *ZIP Code: 99999

*Office Phone Number: 1-866-777-0055 | Extension | Office Fax Number

*Credentials
○ MD ○ DO ◉ APRN[1] ○ PA ○ PharmD

[1] Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse Midwife (CNM).

*Medical Specialty (please select one)
◉ Hematology/Oncology ○ Immunology ○ Internal medicine ○ Nephrology ○ Neurology ○ Rheumatology
○ Other (please specify)

Prescriber Designee Information

Please Note: A prescriber designee is an office contact or administrative support staff for the prescriber's office, who will be able to enter patient vaccination antibacterial drug prophylaxis information on the prescriber's behalf.

First Name | Last Name

Email | Phone

Prescriber Agreement

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

- I have read and understand the VOYDEYA Prescribing Information (PI), **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.

Before treatment initiation, I will:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate VOYDEYA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y and B; and *Streptococcus pneumoniae* and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal and pneumococcal vaccines at least two weeks prior to initiation of treatment and who must start VOYDEYA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 1 week following the last dose of VOYDEYA.

During treatment, I will:

- Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations.

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals, Inc at 1-844-259-6783.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe VOYDEYA.

I understand that VOYDEYA REMS and its agents or contractors may contact me to support the administration of the REMS.

I understand that Alexion or its agents or contractors may use and disclose my information in accordance with the Alexion Privacy Notice, available at www.alexion.com/legal#privacy, including to support the administration of the VOYDEYA REMS.

Clear Signature

Please use your mouse or stylus to sign below

Cancel | Submit

Prescriber Enrollment

VOYDEYA REMS
Prescriber Enrollment Form

Instructions

To become certified in the VOYDEYA REMS and prescribe VOYDEYA™:

1. **Review** the VOYDEYA Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. **Enroll** in the REMS by completing and submitting this form below.

(* Indicates Required Field)

Prescriber Information

*National Provider Identifier (NPI)
1234567890

*First Name: Steve
MI:
*Last Name: Meru
*Email: abc@abc.com

*Clinic/Practice Name: ABC

*Address Line 1: 123 Main Street
Address Line 2:

*City: Philadelphia
*State: PA
*ZIP Code: 99999

*Office Phone Number: 1-866-777-0055
Extension:
Office Fax Number:

*Credentials
○ MD ○ DO ◉ APRN[1] ○ PA ○ PharmD

[1] Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM).

*Medical Specialty (please select one)
○ Hematology/Oncology ○ Immunology ○ Internal medicine ○ Nephrology ○ Neurology ○ Rheumatology ◉ Other (please specify)

*Medical Specialty Other: XYZ

Prescriber Designee Information

Please Note: A prescriber designee is an office contact or administrative support staff for the prescriber's office, who will be able to enter patient vaccination antibacterial drug prophylaxis information on the prescriber's behalf.

First Name:
Last Name:
Email:
Phone:

Prescriber Agreement

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

- I have read and understand the VOYDEYA Prescribing Information (PI), **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.

Before treatment initiation, I will:

- Assess the patient for unresolved serious infections caused by encapsulated bacteria.
- For patients with an unresolved serious infection caused by encapsulated bacteria: Not initiate VOYDEYA.
- Assess the patient's vaccination status for *Neisseria meningitidis* serogroups A, C, W, Y and B; and *Streptococcus pneumoniae* and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
- For patients who are not up to date with meningococcal and pneumococcal vaccines at least two weeks prior to initiation of treatment and who must start VOYDEYA urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
- Counsel the patient on the need to carry the **Patient Safety Card** at all times during treatment and for 1 week following the last dose of VOYDEYA.

During treatment, I will:

- Assess the patient for early signs and symptoms of serious bacterial infection and evaluate immediately, if infection is suspected.
- Vaccinate patients as needed according to the current ACIP recommendations.

At all times, I must:

- Report adverse events suggestive of serious bacterial infections, including the patient's clinical outcomes, to Alexion Pharmaceuticals, Inc at 1-844-259-6783.

I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe VOYDEYA.

I understand that VOYDEYA REMS and its agents or contractors may contact me to support the administration of the REMS.

I understand that Alexion or its agents or contractors may use and disclose my information in accordance with the Alexion Privacy Notice, available at www.alexion.com/legal#privacy, including to support the administration of the VOYDEYA REMS.

Clear Signature

Please use your mouse or stylus to sign below

Cancel | Submit

Prescriber Enrollment Submitted Successfully

Thank you for submitting your information to certify in the VOYDEYA REMS.

A confirmation of this submission, along with a link to create your online account, has been sent via email.

If you do not receive the email, please check junk or spam folders. For further assistance, or to update your registration information at any time, please contact the VOYDEYA REMS at 1-888-765-4747.

Outpatient Pharmacy

VOYDEYA™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), because of the risk of serious infections caused by encapsulated bacteria. VOYDEYA is only available from outpatient pharmacies that are certified in the VOYDEYA REMS.

To become certified, the outpatient pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the certified pharmacy.

The Authorized Representative must complete the following steps:

1

Review the following:

- **Healthcare Provider Safety Brochure**

→

2

Complete and submit the **Outpatient Pharmacy Enrollment Form** to the VOYDEYA REMS

- Pharmacy is required to establish a contract with Alexion and must fill out and submit an **Outpatient Pharmacy Enrollment Form** prior to becoming certified
- Contact the VOYDEYA REMS Call Center at **1-888-765-4747** to obtain the **Outpatient Pharmacy Enrollment Form**

Resources for Outpatient Pharmacies

Healthcare Provider Safety Brochure

Download All Outpatient Pharmacy Resources

ALEXION AstraZeneca Rare Disease

Inpatient Pharmacy

VOYDEYA™ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), because of the risk of serious infections caused by encapsulated bacteria. VOYDEYA is only available from inpatient pharmacies that are certified in the VOYDEYA REMS.

To become certified, the inpatient pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the certified pharmacy.

The Authorized Representative must complete the following steps:

1

Review the following:

- **Healthcare Provider Safety Brochure**

→

2

Complete and submit the **Inpatient Pharmacy Enrollment Form** to the VOYDEYA REMS

- Contact the VOYDEYA REMS Call Center at **1-888-765-4747** to obtain the **Inpatient Pharmacy Enrollment Form**
- Pharmacy must complete and submit an **Inpatient Pharmacy Enrollment Form** prior to becoming certified

Resources for Inpatient Pharmacies

Healthcare Provider Safety Brochure

Download All Inpatient Pharmacy Resources

Prescribing Information Medication Guide LOGIN >

Voydeya™ (danicopan)

Home Healthcare Providers Outpatient Pharmacy Inpatient Pharmacy Certified Participant Locator

Certified Participant Locator

To obtain information on certified pharmacy locations, please contact the REMS Call Center by phone at 1-888-765-4747.

To locate a certified prescriber, please enter a street address, city, state, or ZIP code.

*Find a Certified Prescriber Near

*Search Radius

Within 100 miles

Search >

ALEXION AstraZeneca Rare Disease

Certified Participant Locator

To obtain information on certified pharmacy locations, please contact the REMS Call Center by phone at 1-888-765-4747.

To locate a certified prescriber, please enter a street address, city, state, or ZIP code.

Healthcare Providers

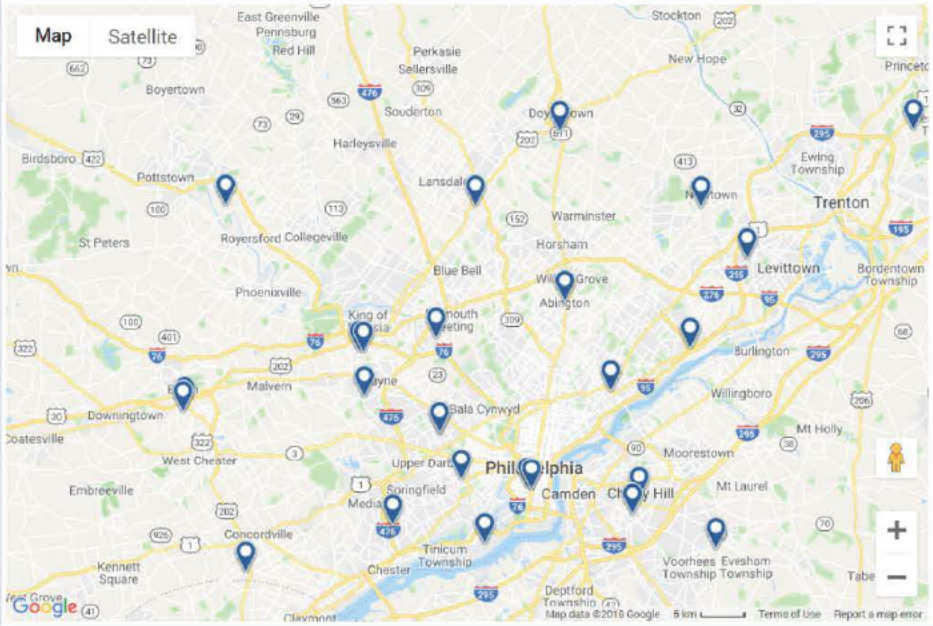
*Find a Certified Prescriber Near

19422

*Search Radius

Within 100 miles

Search



Prescriber Name 75.1 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
Directions

Prescriber Name 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
Directions

Prescriber Name 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
Directions

Prescriber Name 75.6 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
Directions

Prescriber Name 76.2 miles
100 Main St
Blue Bell, PA 19422
555 555-1212
Directions

ALEXION AstraZeneca Rare Disease

Contact Us

Phone
1-888-765-4747

Fax
1-866-750-0785

Email
Voydeya@AlexionREMS.com

Hours of Operation
Monday - Friday
8:00 AM – 8:00 PM EST

ALEXION® AstraZeneca Rare Disease

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/s/

HYLTON V JOFFE
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