Voydeya™
(danicopan) 50mg·100mg tablets

Quick Start Guide to VOYDEYA™ (danicopan)

INDICATION

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

Limitation 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.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

VOYDEYA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Neisseria meningitidis, Streptococcus pneumoniae,* and *Haemophilus influenzae* type B [*see Warnings and Precautions (5.1)*]. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for encapsulated bacteria specifically, *Neisseria meningitidis* and *Streptococcus pneumoniae* at least 2 weeks prior to the first dose of VOYDEYA, unless the risks of delaying therapy with VOYDEYA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by encapsulated bacteria.**
- **Patients receiving VOYDEYA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VOYDEYA REMS [*see Warnings and Precautions (5.2)*].

Please see Important Safety Information and full Prescribing Information for VOYDEYA™ (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.

ALEXION®
AstraZeneca Rare Disease

US/VOY-PNH/0093 V1 04/2024

Help your patient get started on VOYDEYA with these 3 steps

1

Become REMS certified to prescribe VOYDEYA

Due to the risk of serious infections from encapsulated bacteria, prescribers will need to become certified in the VOYDEYA REMS program.

Get certified at VOYDEYArems.com

2

Ensure vaccinations are completed or updated before starting treatment with VOYDEYA

Complete or update vaccinations for encapsulated bacteria at least 2 weeks before starting VOYDEYA and readminister during treatment according to the most recent ACIP recommendations.

See VOYDEYArems.com for more information about vaccine requirements

3

Prescribe VOYDEYA through Onco360, the sole specialty pharmacy

Send the completed and signed VOYDEYA prescription form directly to Onco360, VOYDEYA's sole specialty pharmacy.*

See below for Onco360's support services, contact information and VOYDEYA prescription form

Onco360 is available to provide support and assistance for physicians and office staff

Onco360® ONCOLOGY PHARMACY

Onco360, the sole specialty pharmacy for VOYDEYA, is committed to providing a high degree of communication and coordination with physicians and their offices to ensure a seamless experience.

The team at Onco360 can:

- Complete the full benefit investigation (BI) for VOYDEYA while monitoring the patient's ongoing coverage for changes throughout the benefit year
- Provide support to prescribers and their offices during the prior authorization (PA) process; this includes obtaining information about the PA criteria from the patient's health plan and addressing requirements that arise while Onco360 is completing the BI process
- Educate patients and caregivers on their out-of-pocket costs
- Confirm with the prescriber that the patient's vaccination requirements have been met prior to shipping VOYDEYA
- Provide support if a denial is received
- Follow-up regularly with patients via medication therapy management calls, and schedule refills for VOYDEYA

*Certain laboratory tests related to EVH should be documented before prescribing, as they may be required by a patient's insurance company as part of the prior authorization (PA) process.
ACIP = Advisory Committee on Immunization Practices.
REMS = Risk Evaluation and Mitigation Strategy.

Contact Onco360:

1-877-662-6633
1-877-662-6355
Onco360.com
e-Prescribe: NPI #1679618151

VOYDEYA Prescription Form:

Scan here to download and complete the VOYDEYA prescription form

Alexion OneSource™ is a complimentary, personalized patient support program

ONESOURCE®
Personalized Patient Support from Alexion

Alexion OneSource is available to enrolled adult patients with extravascular hemolysis (EVH) associated with paroxysmal nocturnal hemoglobinuria (PNH).

Financial assistance and access programs:

VOYDEYA 30-Day Free Trial Program

The 30-Day Free Trial Program is an offering for new patients and HCPs who would like to assess tolerability and efficacy of VOYDEYA.†

Free Limited Supply Program

The Free Limited Supply Program is a patient support offering to support commercially insured patients looking to start treatment who are experiencing a coverage delay of 5 days or more due to a payer's approval process. Both OneSource and Onco360 are available to initiate the process for patients.

Third-party Resources

Alexion can connect patients on Medicare, Medicaid, or another federal- or state-funded insurance plan to third-party resources or foundations that may be able to help with financial assistance.

Alexion OneSource™ CoPay Program*

Pay as little as $0 in out-of-pocket costs

Patients can save on their medications if they:

- Do not have Medicare, Medicaid, or other government insurance*
- Are enrolled in OneSource™
- Have commercial insurance that covers some portion of the drug cost
- Have a valid VOYDEYA prescription
- Are a citizen or permanent resident of the United States or its territories

Enrollment in OneSource enables:

- ☑ Product and disease state education
- ☑ Comprehensive vaccination support (vaccination information, locations, and logistics)
- ☑ Coordination with your healthcare provider and specialty pharmacy to ensure you keep receiving your medicine as prescribed
- ☑ Insurance coverage support (benefit verification, appeals, and more)
- ☑ Assistance with addressing financial concerns or gaps in coverage
- ☑ Field Reimbursement Managers/OneSource Support Specialists to provide ongoing case-specific support

*The Alexion OneSource™ CoPay Program is not valid for costs eligible to be reimbursed by government insurance programs or other federal or state programs (including any state prescription drug assistance programs), including Medicaid, Medicare (including Medicare Part D), Medicare Advantage plans, Medigap, Veterans Affairs, Department of Defense, or TRICARE.
†Before registering patients for the VOYDEYA 30-Day Free Trial Program, prescribers should ensure all prior authorization (PA) criteria have been met to support a successful transition to commercial product.

Contact OneSource™:

1-888-765-4747
AlexionOneSource.com

OneSource™ Brochure:

Scan here to download and view the OneSource™ brochure

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INDICATION & IMPORTANT SAFETY INFORMATION FOR VOYDEYA™ (danicopan)

INDICATION

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- **Complete or update vaccination for encapsulated bacteria specifically, *Neisseria meningitidis* and *Streptococcus pneumoniae* at least 2 weeks prior to the first dose of VOYDEYA, unless the risks of delaying therapy with VOYDEYA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor. See *Warnings and Precautions (5.1)* for additional guidance on the management of the risk of serious infections caused by encapsulated bacteria.**
- **Patients receiving VOYDEYA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VOYDEYA REMS [*see Warnings and Precautions (5.2)*].

CONTRAINDICATIONS

Initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Neisseria meningitidis, Streptococcus pneumoniae,* or *Haemophilus influenzae* type B.

WARNINGS AND PRECAUTIONS

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.

Complete, update, or revaccinate patients in accordance with ACIP recommendations considering the duration of VOYDEYA therapy. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. 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 antibacterial drug prophylaxis and administer these vaccines as soon as possible. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including VOYDEYA. The benefits and risks of treatment with VOYDEYA, as well as those associated with antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

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 infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of VOYDEYA in patients who are undergoing treatment for serious infections.

VOYDEYA REMS

Due to the risk of serious infections caused by encapsulated bacteria, VOYDEYA is available only through a restricted program called VOYDEYA REMS. Per the REMS requirements:

Prescribers must enroll in the REMS, counsel patients about the risk of serious infections caused by encapsulated bacteria, provide patients with the REMS educational materials, assess patient vaccination status for vaccines against encapsulated bacteria, and vaccinate if needed according to current ACIP recommendations 2 weeks prior to the first dose of VOYDEYA. Antibacterial drug prophylaxis must be prescribed if treatment must be started urgently and the patient is not up to date with vaccines against encapsulated bacteria according to current ACIP recommendations at least 2 weeks prior to the first dose of VOYDEYA.

Pharmacies that dispense VOYDEYA must be certified in the VOYDEYA REMS and must verify prescribers are certified.

Patients must receive counseling from the prescriber about the need to receive vaccinations against encapsulated bacteria per ACIP recommendations, to take antibiotics as directed, the early signs and symptoms of serious infection, and be instructed to carry the Patient Safety Card at all times during and for 1 week following the last dose of VOYDEYA.

Further information is available at www.voydeyarems.com or 1-888-765-4747.

Hepatic Enzyme Increases

Hepatic enzyme elevations have been observed in patients treated with VOYDEYA. A total of 14% of patients receiving VOYDEYA had elevations in serum alanine aminotransferase (ALT). ALT elevations >3× the upper limit of normal (ULN) and ≤5× ULN occurred in 9% of VOYDEYA-treated patients, and ALT elevations >5× ULN and ≤10× ULN occurred in 5% of VOYDEYA-treated patients.

Assess liver enzyme test results prior to the initiation of VOYDEYA and periodically during treatment. Consider treatment interruption or discontinuation if elevations are clinically significant or if the patient becomes symptomatic. VOYDEYA has not been studied in patients with severe hepatic impairment.

Monitoring of PNH Manifestations After VOYDEYA Discontinuation

After discontinuing treatment with VOYDEYA, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis. If discontinuation of VOYDEYA is necessary, continue background treatment with ravulizumab or eculizumab or consider alternative therapy if necessary. The signs and symptoms of hemolysis may include sudden decrease in hemoglobin or fatigue.

If hemolysis occurs after discontinuation of VOYDEYA, consider restarting treatment with VOYDEYA, if appropriate.

Hyperlipidemia

VOYDEYA increases total cholesterol and LDL-cholesterol. Of the 50 VOYDEYA-treated patients who had a normal total cholesterol level at baseline, 30% developed Grade 1 hypercholesterolemia. Of the 6 VOYDEYA-treated patients who had Grade 1 hypercholesterolemia at baseline, 1 patient experienced increased total cholesterol that worsened to Grade 2. Of the 54 VOYDEYA-treated patients who had LDL-cholesterol ≤130 mg/dL at baseline, 13% developed LDL-cholesterol >130-160 mg/dL, and 9% developed LDL-cholesterol >160-190 mg/dL.

Some patients required cholesterol-lowering medications. Monitor serum lipid parameters periodically during treatment with VOYDEYA and initiate cholesterol-lowering medication, if indicated.

ADVERSE REACTIONS

The most common adverse reaction reported in ≥10% of patients treated with VOYDEYA was headache. Serious adverse reactions were reported in 5% of patients who received VOYDEYA and included pancreatitis, cholecystitis, and increased blood bilirubin. No specific serious adverse reaction was reported in more than 1 patient treated with VOYDEYA. Adverse reactions reported in ≥5% of patients treated with VOYDEYA and greater than placebo in the randomized, controlled period included vomiting, pyrexia, increased alanine aminotransferase, hypertension, and pain in the extremities. Clinically relevant adverse reactions in <5% of patients included increased serum triglycerides.

DRUG INTERACTIONS

BCRP Substrates

Danicopan is a Breast Cancer Resistance Protein (BCRP) inhibitor. Concomitant use of VOYDEYA with a BCRP substrate increases the plasma concentrations of the BCRP substrate, which may increase the risk for adverse reactions associated with the BCRP substrate. If used together, monitor patients more frequently for adverse reactions, associated with the BCRP substrate and consider dose reduction of the BCRP substrate according to its prescribing information.

Rosuvastatin

Danicopan significantly increased rosuvastatin exposure. The dose of rosuvastatin should not exceed 10mg once daily when concomitantly used with VOYDEYA.

P-glycoprotein Substrates

Danicopan is an inhibitor of P-glycoprotein (P-gp). Concomitant administration of VOYDEYA with P-gp substrates may increase the plasma concentrations of the P-gp substrates. Dose adjustment might be necessary for P-gp substrates where minimal concentration changes may lead to serious adverse reactions.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on VOYDEYA use in pregnant individuals to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with untreated PNH in pregnancy. The use of VOYDEYA in pregnant women or women planning to become pregnant may be considered following an assessment of the risks and benefits.

Lactation

There are no data on the presence of VOYDEYA in human milk, the effects on the breastfed child, or the effect on milk production. VOYDEYA is present in animal milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Because of the potential for serious adverse reactions in the breastfed child, including serious infections with encapsulated bacteria and liver enzyme increases, advise patients not to breastfeed during treatment with VOYDEYA and for 3 days after the last dose.

Hepatic Impairment

No dose adjustment is required in patients with mild to moderate hepatic impairment. Studies have not been conducted in patients with severe hepatic impairment, therefore, avoid use of VOYDEYA in this patient population.

To report SUSPECTED ADVERSE REACTIONS, contact Alexion Pharmaceuticals, Inc. at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information for VOYDEYA (danicopan), including Boxed WARNING regarding serious and life-threatening or fatal infections.

This material is intended only for residents of the United States.

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