

MEDICATION GUIDE
VOYDEYA™(voi-day-uh)
(danicopan)
tablets, for oral use

What is the most important information I should know about VOYDEYA?

VOYDEYA is a medicine that affects your immune system. VOYDEYA 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 meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae type B*. These serious infections may quickly become life-threatening and cause death if not recognized and treated early.
 - 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. **Call your healthcare provider or get emergency medical care right away if you have 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

Your healthcare provider will give you a Patient Safety Card about the risk of serious infections. Carry it 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. If you get any of the symptoms listed on this card you should get medical help right away. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

- **VOYDEYA is only available through a program called the VOYDEYA REMS.** Before you can take VOYDEYA, your healthcare provider must:
 - enroll in the VOYDEYA REMS.
 - counsel you about the risk of serious infections caused by certain bacteria.
 - give you information about the symptoms of serious infections.
 - make sure that you are vaccinated against serious infections caused by encapsulated bacteria and that you receive antibiotics if you need to start VOYDEYA right away and you are not up to date on your vaccinations.
 - give you a Patient Safety Card about your risk of serious infections, as discussed above.

For more information about side effects, see **“What are the possible side effects of VOYDEYA?”**

What is VOYDEYA?

VOYDEYA 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). It is not known if VOYDEYA is safe and effective in children.

Who should not take VOYDEYA?

Do not take VOYDEYA if you have a serious infection caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, or *Haemophilus influenzae type B* when you are starting VOYDEYA treatment.

Before taking VOYDEYA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever
- have liver problems

- are pregnant or plan to become pregnant. It is not known if VOYDEYA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VOYDEYA passes into your breast milk. Do not breastfeed during treatment with VOYDEYA and for 3 days after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VOYDEYA may affect the way other medicines work.

Know the medicines you take and the vaccines you receive. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take VOYDEYA?

- Take VOYDEYA exactly as your healthcare provider tells you to take it.
 - Depending on the dose prescribed, the number of tablets is as follows:
 - 150 mg dose: take 1 tablet of 100 mg and 1 tablet of 50 mg together 3 times a day.
 - 200 mg dose: take 2 tablets of 100 mg 3 times a day.
 - Do not change the dose or stop taking VOYDEYA unless your healthcare provider tells you.
 - Take VOYDEYA by mouth.
 - Take VOYDEYA with or without food.
 - Take your doses of VOYDEYA around the same time every day.
 - If you forget to take your scheduled dose, take it as soon as you remember. If it is within 3 hours of your next dose, skip the missed dose and take your next scheduled dose at your regularly scheduled time. Do not take 2 doses of VOYDEYA at the same time.
 - If you take too much VOYDEYA, call your healthcare provider or go to the nearest emergency room right away.
 - **If you stop taking VOYDEYA**, your healthcare provider will need to monitor you closely for at least 2 weeks after the last dose. **Stopping treatment with VOYDEYA may cause a breakdown of red blood cells due to PNH.**
- Symptoms or problems that can happen due to breakdown of red blood cells include:**
- decreased hemoglobin level in your blood
 - tiredness

What are the possible side effects of VOYDEYA?

VOYDEYA may cause side effects, including:

- See “**What is the most important information I should know about VOYDEYA?**”
- **Increased liver enzyme levels.** Your healthcare provider will do blood tests to check your liver enzyme levels before and during treatment with VOYDEYA. Your healthcare provider may temporarily or permanently stop treatment with VOYDEYA if you develop increased liver enzyme levels.
- **Increased cholesterol.** VOYDEYA may increase your cholesterol. Your healthcare provider will do blood tests to check your cholesterol during treatment with VOYDEYA.

The most common side effect of VOYDEYA is headache.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all of the possible side effects of VOYDEYA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VOYDEYA?

- Store VOYDEYA in the original container between 68°F and 77°F (20°C and 25°C).
- **Keep VOYDEYA and all medicines out of the reach of children.**

General information about the safe and effective use of VOYDEYA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VOYDEYA for a condition for which it was not prescribed. Do not give VOYDEYA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VOYDEYA that is written for health professionals.

What are the ingredients in VOYDEYA?

Active ingredient: danicopan

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The film coatings contain the following inactive ingredients: polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufactured for: Alexion Pharmaceuticals, Inc., 121 Seaport Boulevard, Boston, MA 02210 USA

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For more information, go to www.VOYDEYA.com or call 1-888-765-4747.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 03/2024