

Voydeya

Pronunciation: *voi-day-uh*Generic name: danicopan
Dosage form: oral tablets

Drug class: Selective immunosuppressants

Medically reviewed by Carmen Pope, BPharm. Last updated on Apr 16, 2024.

What is Voydeya?

Voydeya (danicopan) is an oral complement factor D inhibitor that may be used to treat extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH) as add-on therapy to ravulizumab (Ultomiris) or eculizumab (Soliris) when patients have had an insufficient response to these treatments.

Voydeya addresses the needs of 10-20% of patients with PNH who experience clinically significant EVH despite treatment with a C5 inhibitor. EVH involves the destruction of red blood cells outside of the blood vessels.

Voydeya (danicopan) works by specifically binding to complement Factor D (part of the immune system) which plays a key role in the formation of the alternative pathway, which can result in an over responsive complement system and the body attacking its own cells. It prevents its cleavage into Ba and Bb fragments that are required for the formation of an enzyme involved in EVH. Co-administered ravulizumab or eculizumab helps maintain control over membrane attack complex (MAC)-mediated intravascular hemolysis (IVH) – which is the destruction of red blood cells inside the blood vessels.

Voydeya was FDA approved on 29 March 2024.

What are the side effects of Voydeya?

Voydeya can cause serious and life-threatening side effects, including an increased risk of infections (see warnings below).

The **most common side effect** of Voydeya affecting 10% or more people 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 the FDA at 1-800-FDA-1088.

Voydeya side effects (more detail)

Related/similar drugs

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Warnings and serious effects

Voydeya increases the risk of serious and life-threatening infections, caused by encapsulated bacteria, including *Neisseria meningitidis*, *Streptococcus pneumoniae*, and *Haemophilus influenzae* type B.

 Vaccination for these bacteria should be completed at least 2 weeks before the first dose of Voydeya unless the risks of delaying this treatment outweigh the risk of developing a serious infection. Your healthcare provider will advise you about this and you should report any signs of infection, such as fever, rash, chills, cough, shortness of breath, or body aches with flu-like symptoms.

Voydeya can increase liver enzymes and blood lipid levels. It should not be used in patients with severe hepatic impairment (Child-Pugh C). Your healthcare provider will measure your liver enzymes and lipids before treatment and monitor them regularly throughout.

Voydeya is available only through a restricted program called Voydeya REMS. Before you can take it, your healthcare provider must:

- enroll you in the REMS program.
- 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.

Voydeya has not been shown to be effective as monotherapy and should only be prescribed as an add-on treatment to ravulizumab (Ultomiris) or eculizumab (Soliris).

It is not known if Voydeya is safe and effective in children.

Before taking

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

- · have an infection or fever
 - Voydeya should not be taken if you currently have a serious infection caused by encapsulated bacteria, including *N. meningitidis*, *S. pneumoniae*, or *H. influenzae* type B.
- · have liver problems
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

Pregnancy

It is not known if Voydeya will harm your unborn baby because there has been no studies in pregnant women. But there are risks to pregnant women and their unborn baby associated with untreated PNH in pregnancy. Talk with your healthcare provider about the risks and benefits. Tell your healthcare provider right away if you are pregnant or become pregnant while taking Voydeya.

Breastfeeding

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.

1 Voydeya pregnancy and breastfeeding warnings (more detail)

How should I take Voydeya?

Take it exactly as your healthcare provider tells you to take it. Voydeya is taken by mouth.

- The usual starting dose is 150mg three times a day.
- Your healthcare provider may adjust this dose depending on your response.
- You can take Voydeya with or without food.

Voydeya is available as 50mg or 100mg tablets. 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.

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. 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.

Detailed Voydeya dosage information

What happens if I miss a dose?

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.

What happens if I overdose?

If you take too much Voydeya, call your healthcare provider or go to the nearest emergency room right away.

Other information

If you stop taking Voydeya, your healthcare provider monitor you closely for at least 2 weeks after the last dose.

- Stopping treatment may cause a breakdown of red blood cells due to PNH.
- Symptoms or problems that can happen due to the breakdown of red blood cells include tiredness and decreased levels of hemoglobin level in your blood.

What other drugs will affect Voydeya?

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.

- Voydeya may increase the risk of side effects associated with BCRP substrates (such as methotrexate, irinotecan, or nitrofurantoin). For rosuvastatin, the dose should not exceed 10 mg once daily.
- Dosage adjustments may be needed for P-gp substrates, such as apixaban, colchicine, cyclosporine, dabigatran, or digoxin, where minimal concentration changes may lead to serious side effects.

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. See the prescribing information for a full list of interactions.

1 Voydeya drug interactions (more detail)

Storage

Store in the original container at room temperature (between 68°F and 77°F [20°C and 25°C]).

Keep out of the reach of children.

Voydeya ingredients

Active ingredient: danicopan

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

Film coating: polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Manufacturer

Alexion Pharmaceuticals, Inc.

References

1. Product Label

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.