

MEDICATION GUIDE
VEOPOZ™ (VEE-oh-poz)
(pozelimab-bbfg)
injection, for intravenous or subcutaneous use

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

VEOPOZ is a medicine that affects your immune system. VEOPOZ can lower the ability of your immune system to fight infections.

- VEOPOZ increases your chance of getting serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.
1. You must receive meningococcal vaccines at least 2 weeks before your first dose of VEOPOZ if you have not already had these vaccines.
 2. If you had a meningococcal vaccine in the past, you might need additional vaccination before starting VEOPOZ. Your healthcare provider will decide if you need additional meningococcal vaccination.
 3. If your healthcare provider decided that urgent treatment with VEOPOZ is needed, and your meningococcal vaccines are not up-to-date, you should receive meningococcal vaccination as soon as possible. You should also receive antibiotics.
 4. Meningococcal vaccines reduce the risk of meningococcal infection but do not prevent all meningococcal infections. Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a meningococcal infection:
 - headache with nausea or vomiting
 - headache with a stiff neck or stiff back
 - fever and a rash
 - muscle aches with flu-like symptoms
 - headache and fever
 - fever
 - confusion
 - eyes sensitive to light

Your healthcare provider will give you a Patient Safety Card about the symptoms of meningococcal, or other infection. Carry it with you at all times during treatment and for 3 months after your last VEOPOZ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of VEOPOZ. It is important to show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.

VEOPOZ may also increase the risk of other types of serious bacterial infections.

- People who take VEOPOZ may have an increased risk of getting infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.
- Certain people may also have an increased risk of bacterial infections including gonorrhea infection. Talk to your healthcare provider to find out if you are at risk of gonorrhea infection, about gonorrhea prevention, and regular testing.

Call your healthcare provider right away if you have any new signs or symptoms of infection.

What is VEOPOZ?

VEOPOZ is a prescription medicine called a monoclonal antibody. VEOPOZ is used to treat adults and children 1 year of age and older with a disease called CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

It is not known if VEOPOZ is safe and effective in children younger than 1 year of age.

Do not receive VEOPOZ if you:

- have a meningococcal infection.

Before you receive VEOPOZ, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- are pregnant or plan to become pregnant. It is not known if VEOPOZ will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VEOPOZ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with VEOPOZ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

It is important that you:

- have all recommended vaccinations before you start VEOPOZ.
- receive antibiotics if you start VEOPOZ within 2 weeks of receiving meningococcal vaccination.
- stay up to date with all recommended vaccinations during treatment with VEOPOZ.

VEOPOZ and other medicines may affect each other causing side effects. VEOPOZ may affect the way other medicines work, and other medicines may affect how VEOPOZ works.

Especially tell your healthcare provider if you take Intravenous Immunoglobulin (IVIg).

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 receive VEOPOZ?

- The first dose of VEOPOZ is given through a vein (I.V. or intravenous infusion) usually over 1 hour or more, depending on your weight. If you have an allergic reaction during your VEOPOZ infusion, your healthcare provider may decide to give VEOPOZ more slowly or stop your infusion.
- You will then receive VEOPOZ one time each week starting on day 8 after the first dose, as an injection under the skin (subcutaneous injection).
- After the infusion and your first subcutaneous injection, you will be monitored for 30 minutes for allergic reactions.
- If you miss receiving a VEOPOZ subcutaneous dose, call your healthcare provider right away to find out when you will receive your next injection.

What are the possible side effects of VEOPOZ?

VEOPOZ can cause serious side effects including:

- See “**What is the most important information I should know about VEOPOZ?**”
- **Allergic (hypersensitivity) reactions.** Allergic reactions, including infusion-related reactions, may happen during your VEOPOZ intravenous or subcutaneous treatment. Tell your healthcare provider right away if you develop the following symptoms, or any other symptoms during your VEOPOZ treatment that may mean you are having a serious allergic reaction:
 - chest pain
 - swelling of your face, tongue, or throat
 - trouble breathing or shortness of breath
 - feel faint or pass out

The most common side effects of VEOPOZ are:

- upper respiratory tract infection
- fracture
- raised, red patches of skin that are often very itchy (hives)
- hair loss (alopecia)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of VEOPOZ. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of VEOPOZ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about VEOPOZ that is written for health professionals.

What are the ingredients in VEOPOZ?

Active ingredient: pozelimab-bbfg.

Inactive ingredients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and Water for Injection.

Manufactured by:

Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591 U.S. License No. 1760

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For more information about VEOPOZ, go to www.VEOPOZ.com or call 1-855-5VEOPOZ (1-855-583-6769).

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

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