

EXPLORE VEOPOZ

The first and only FDA-approved treatment for patients 1 year and older with a disease called CD55-deficient protein-losing enteropathy, also known as CHAPLE disease.

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

Not actual patients.

Learn more about CHAPLE disease and a potential treatment option called VEOPOZ for your child.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about VEOPOZ? VEOPOZ is a medicine that affects your immune system and can lower the ability of your immune system to fight infections.

- VEOPOZ increases your chance of getting serious and life-threatening meningococcal infections that 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.
 - 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.
 - If your healthcare provider decides 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

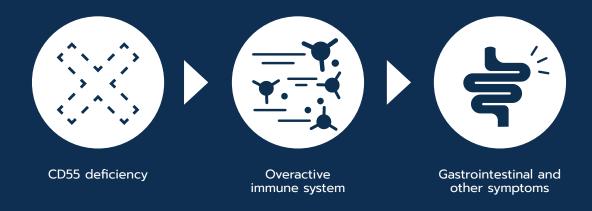
Your healthcare provider will give you a Patient Safety Card about the symptoms of meningococcal or other infections. Carry it with you at all times during treatment and for 3 months after your last VEOPOZ dose. Your risk of meningococcal infection may continue for several weeks after your last dose 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.

WHAT IS **CHAPLE DISEASE?**

CD55 is a protein that helps regulate a part of the immune system called the complement system. Changes to DNA, called mutations, can limit the functional activity of the CD55 protein, resulting in overactivity of the immune system. This can lead to damage in the gastrointestinal tract, protein loss (including serum albumin, a protein that is key for regulation of the immune system), and CHAPLE symptoms.

Symptoms of CHAPLE disease include:

- Abdominal pain
- Diarrhea
- Swelling of the arms/hands, face, and legs/feet



IMPORTANT SAFETY INFORMATION (continued)

What is the most important information I should know about VEOPOZ? (continued) 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 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.

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, and are breastfeeding or plan to breastfeed. It is not known if VEOPOZ will harm your unborn baby or if it passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with VEOPOZ.

HOW DOES VEOPOZ WORK?



VEOPOZ is a prescription medicine called a monoclonal antibody that targets a specific protein (complement protein C5) in the body. By targeting C5, VEOPOZ can help treat some of the damaging effects of CD55 deficiency.

HOW CAN VEOPOZ **HELP MY CHILD** WITH CHAPLE DISEASE?



In a clinical study, 10 patients ranging from 3 to 19 years old with active signs and symptoms of CHAPLE disease were given VEOPOZ. Prior to VEOPOZ treatment, all of the patients received meningococcal vaccination as well as antibiotics for prophylaxis of meningococcal infection.

In a clinical study, patients treated with VEOPOZ experienced:



Normalization of serum albumin by Week 12*



Fewer hospitalization days after 48 weeks of treatment[†]



Fewer albumin transfusions after 48 weeks of treatment[‡]



Normalization of serum IgG concentrations by Week 12§

Individual results may vary. Speak with your physician to learn more about how VEOPOZ can help your child living with CHAPLE disease.

IgG=immunoglobulin G.

- *The median time for serum albumin to reach normal levels was 15.5 days (N=10; 95% CI: 8 to 28). All 10 patients maintained serum albumin levels within normal range through at least 72 weeks of treatment.
- [†]Nine of the 10 patients were hospitalized for a total of 268 days in the 48 weeks prior to treatment. In the 48 weeks after starting treatment, two patients were hospitalized for a total of 7 days.
- [‡]Five of the 10 patients received a total of 60 transfusions in the 48 weeks prior to treatment. In the 48 weeks after starting treatment, one patient received one albumin transfusion.
- ⁵Serum IgG is a type of antibody that plays a role in your immune system. All 10 patients maintained improvement in serum IgG levels through at least 72 weeks of treatment.

IMPORTANT SAFETY INFORMATION (continued)

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, and stay up to date with all recommended vaccinations during treatment with VEOPOZ.



WHAT SHOULD I KNOW BEFORE MY CHILD **STARTS**VEOPOZ TREATMENT?



Before patients receive VEOPOZ, their healthcare provider should be informed about all of their medical conditions, including if patients:

- have an infection or fever
- are pregnant or plan to become pregnant*
- are breastfeeding or plan to breastfeed*

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.† Especially tell your healthcare provider if they take intravenous immunoglobulin (IVIg).

It is important that your child:

- has all recommended vaccinations before they start VEOPOZ[‡]
- receive antibiotics if they start VEOPOZ within 2 weeks of receiving meningococcal vaccination
- stay up to date with all recommended vaccinations during treatment with VEOPOZ

Your child should not receive VEOPOZ if they have a meningococcal infection.

- *It is not known if VEOPOZ will harm an unborn baby or if VEOPOZ passes into breast milk. Patients who are breastfeeding or planning to breastfeed should talk to their healthcare provider about the best way to feed their baby during treatment with VEOPOZ.
- [†]Keep a list of the medicines your child takes and the vaccines they receive to show your healthcare provider and pharmacist when you get a new medicine for your child.
- *Your child's vaccinations should comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients receiving a complement inhibitor. For further guidance, speak to your healthcare provider and see "What is the most important information I should know about VEOPOZ?" on pages 6 and 7.

IMPORTANT SAFETY INFORMATION (continued)

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.

Veopoz

Injection

(pozelimab-bbfg)

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.

WHAT DOES **TREATMENT** WITH VEOPOZ LOOK LIKE?

The first dose of VEOPOZ is given through a vein (intravenous infusion, or IV) and usually takes 1 hour or more, depending on your child's weight. If your child has an allergic reaction during their VEOPOZ infusion, your healthcare provider may decide to give VEOPOZ more slowly or stop their infusion.

Your child will then receive VEOPOZ one time each week starting on Day 8 after the first dose, as an injection under the skin (subcutaneous injection).

1.

First dose

- Must be given through a vein (IV) by a healthcare provider
- Infusion usually takes over 1 hour or more depending on your child's weight
- Your child will be asked to stay for 30 minutes after the infusion to watch out for allergic reactions, which can be serious. See page 7 for more information



2.)

Weekly follow-up subcutaneous injections

- Begin on Day 8 (1 week after first dose)
- Can take place in a doctor's office or at home, but must be administered by a healthcare provider
- Based on your child's weight, your doctor will determine if they need 1 or 2 injections
- Your child will be asked to stay for 30 minutes after the first follow-up injection to watch out for allergic reactions, which can be serious. See page 7 for more information
- If your child misses receiving a VEOPOZ dose, call your healthcare provider right away to find out when your child will receive their next injection



IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of VEOPOZ?

VEOPOZ can cause serious side effects including allergic (hypersensitivity) reactions, including infusion-related reactions, which may happen during your treatment. Tell your healthcare provider right away if you develop any of these symptoms or any other symptoms during your VEOPOZ treatment that may mean you are having a serious allergic reaction: chest pain, trouble breathing or shortness of breath, swelling of your face, tongue, or throat, or feel faint or pass out.



WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT **VEOPOZ?**

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

Meningococcal infections

VEOPOZ increases your child's chance of serious and life-threatening meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

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- If your child had a meningococcal vaccine in the past, they might need additional vaccination before starting VEOPOZ. Your healthcare provider will decide if your child needs additional meningococcal vaccination
- If your healthcare provider decides that urgent treatment with VEOPOZ is needed, and your child's meningococcal vaccines are not up-to-date, your child should receive meningococcal vaccination as soon as possible. They should also receive antibiotics
- 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 your child gets 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 provide a Patient Safety Card about the symptoms of meningococcal or other infections. It should be carried at all times during treatment and for 3 months after the last VEOPOZ dose. Meningococcal infection risk may continue for several weeks after the last dose of VEOPOZ. It is important to show this card to any treating healthcare provider. This will help them diagnose and treat quickly.



WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT **VEOPOZ?** (continued)

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 (eg, those who are sexually active) may also have an increased risk of bacterial infections including gonorrhea infection. Talk to your healthcare provider to find out about the risk of gonorrhea, prevention, and regular testing.

Call your healthcare provider right away if your child has any new signs or symptoms of infection.

Possible side effects from VEOPOZ

VEOPOZ can cause serious side effects, including allergic (hypersensitivity) reactions. Tell your healthcare provider right away if your child develops any symptoms during VEOPOZ treatment that may indicate a serious allergic reaction, including:

- Chest pain
- Trouble breathing or shortness of breath
- Swelling of the face, tongue, or throat
- Feeling faint or passing out

The most common side effects reported during treatment with VEOPOZ were:

- Upper respiratory tract infection
- Fracture
- Raised, red patches of skin that are often very itchy (hives)
- Hair loss (alopecia)

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of VEOPOZ are upper respiratory tract infection, fracture, raised, red patches of skin that are often very itchy (hives), and hair loss (alopecia).









If you have questions for us, call myRARE: 1-855-5VEOPOZ.

The myRARE Patient Support Program is here to help! Our team will review with you the required information regarding treatment with VEOPOZ.

There is additional optional support available through myRARE, including:



Dedicated Patient Navigator to support patients and their caregivers through their treatment experience



Help understanding and planning for VEOPOZ treatment



Help reviewing your insurance benefits and any financial support needs you may have related to VEOPOZ treatment

IMPORTANT SAFETY INFORMATION (continued)

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 healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please click here for full <u>Prescribing Information</u>, including Boxed WARNING, and <u>Medication Guide</u>.

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