

## Ravulizumab-cwvz (Ultomiris)

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### About This Drug

Ravulizumab-cwvz is used to treat some blood disorders and nerve disorders. It is given in the vein (IV) or as an injection under the skin (subcutaneously).

### Possible Side Effects

- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Injection site reaction – you may get a rash, swelling or bruising or your skin may get red, warm itchy, or painful at the site of your injection
- Fever
- Headache
- Upper respiratory tract infection
- High blood pressure

**Note:** Each of the side effects above was reported in 10% or greater of patients treated with ravulizumab-cwvz. Your side effects may be different depending on your specific condition and/or whether you are receiving it IV or subcutaneously. Not all possible side effects are included above.

### Warnings and Precautions

- Risk of severe meningitis and other infections, which may be life-threatening.
- While you are getting this drug, you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, bad taste in your mouth, rash, itching, pain in your lower back, arms, or legs, chest tightness, or chest pain. These reactions may happen after your infusion and/or injection. **If this happens, call 911 for emergency care.**
- Breakdown of your red blood cells can happen once you have completed your treatment, which may cause anemia and other complications. You will be followed closely by your doctor for several weeks after your treatment has ended.
- Damage to small blood vessels can happen once you have completed your treatment, which can cause bleeding, and blood clots, and can be life threatening. You will be followed closely by your doctor for several weeks after your treatment has ended.

- The on-body injector (OBI) uses acrylic adhesive. Caution should be used if you have an allergy to acrylic adhesives.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

## Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- Meningococcal vaccination is required if you have not already had this vaccine at least 2 weeks prior to receiving treatment with ravulizumab-cwvz or as soon as possible if urgent therapy is needed. If you need urgent therapy, you should also receive 2 weeks of antibiotics with your vaccination. Talk to your doctor and/or nurse about vaccination.
- You will need to sign up for a special program called Ultomiris REMS when you start taking this drug. Your nurse will help you get started.
- You will be given an Ultomiris Patient Safety Card about the risk of meningococcal infection that you should carry with you at all times during treatment and for 8 months after your last dose. Show this card to any doctor or nurse who treats you.

## How to Take Your Medication

### For the on-body injector only:

- Talk to your doctor, nurse, and/or pharmacist for proper preparation, dosing, and administration if you are self-injecting this medicine.
- You will need 2 on-body injectors for a full dose, each injection will take about 10 minutes.
- Do not shake or drop the medicine. You need take it out of the refrigerator at least 45 minutes before use to allow it to come to room temperature.
- **Missed dose:** If you miss a dose, contact your physician right away.
- **Handling:** Wash your hands after before and after handling your OBI. Your caretakers should not handle your OBI with bare hands and should wear latex gloves.
- The OBI is not made with natural rubber latex.
- You or your caregiver can administer the injections at the same time, or 1 after the other into your abdomen, thigh, or upper arm. Injection sites should be rotated and should not be given into areas that are tender, bruised, red, or hard.
- **Storage:** Store this medicine in the refrigerator between 36°F to 46°F (2°C to 8°C). Do not freeze. Store this medicine in the original carton to protect it from light and physical damage. Do not shake or drop. Keep the carton dry and do not allow the OBI to get wet from water or other liquids.
- If removed from the refrigerator, store this medicine at room temperature 68°F to 77°F (20°C to 25°C) for up to 3 days. Throw away after 3 days. Do not return to the refrigerator.



- **Disposal:** Discuss with your nurse or your doctor how to dispose the OBI.

## Treating Side Effects

- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Reactions may occur after your infusion and/or injection. If you have a reaction with the OBI, remove it right away to stop the injection. **If this happens, call 911 for emergency care.**
- While you are getting this drug, please tell your nurse right away if you get a rash, swelling or bruising or your skin gets red, warm, itchy or painful at the site of your injection.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop diarrhea.

## Food and Drug Interactions

- There are no known interactions of ravulizumab-cwvz with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Headache that does not go away
- Confusion
- Blurry vision or other changes in eyesight
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911**



- Signs of meningitis: severe headache, a stiff and painful neck, fever, vomiting, feeling very sleepy and/or seizures
- Wheezing and/or trouble breathing
- Pain in your chest
- Coughing up yellow, green, or bloody mucus
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Easy bleeding or bruising
- Decreased or very dark urine
- Your leg is swollen, red, warm and/or painful
- Signs of breakdown of your red blood cells: tiredness, blood in urine, pain in your abdomen, blood clots, trouble breathing, difficulty swallowing and/or impotence (in men)
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of infusion/injection reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, bad taste in your mouth, rash, itching, pain in your lower back, arms or legs, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- If you think you may be pregnant

## Reproduction Warnings

- **Pregnancy warning:** It is not known if this drug may harm an unborn child. For this reason, be sure to talk with your doctor if you are pregnant or planning to become pregnant while receiving this drug. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 8 months after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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