

MEDICATION GUIDE

OCREVUS ZUNOVO™ (OH-creh-vus zoo-NOH-voh)
(ocrelizumab and hyaluronidase-ocsq)
injection, for subcutaneous use

What is the most important information I should know about OCREVUS ZUNOVO?

OCREVUS ZUNOVO can cause serious side effects, including:

- **Injection reactions:** Injection reactions are a common side effect of OCREVUS ZUNOVO, which can be serious and may require you to be hospitalized. You will be monitored for signs and symptoms of an injection reaction when you receive OCREVUS ZUNOVO. This will happen during all injections, for at least 1 hour after your first injection, and for at least 15 minutes after all injections following the first injection. Tell your healthcare provider or nurse if you get any of these symptoms:

- itchy skin
- rash
- hives
- tiredness
- coughing or wheezing
- trouble breathing
- throat irritation or pain
- feeling faint
- fever
- redness on your face (flushing)
- nausea
- headache
- swelling of the throat
- dizziness
- injection site pain, swelling or redness
- shortness of breath
- fatigue
- fast heart beat

These injection reactions can happen during or up to 24 hours after your injection. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each injection.

- **Infection:**

- Infections are a common side effect. OCREVUS ZUNOVO increases your risk of getting upper respiratory tract infections, lower respiratory tract infections, skin infections, and herpes infections. Serious infections can happen with OCREVUS ZUNOVO, which can be life-threatening or cause death. Tell your healthcare provider if you have an infection or have any of the following signs of infection including fever, chills, or a cough that does not go away, or painful urination. Signs of herpes infection include:

- cold sores
- shingles
- genital sores
- skin rash
- pain
- itching

Signs of a more serious herpes infection include:

- changes in vision
- eye redness or eye pain
- severe or persistent headache
- stiff neck
- confusion

Signs of infection can happen during treatment or after you have received your last dose of OCREVUS ZUNOVO. Tell your healthcare provider right away if you have an infection. Your healthcare provider should delay your treatment with OCREVUS ZUNOVO until your infection is gone.

- **Hepatitis B virus (HBV) reactivation:** Before starting treatment with ocrelizumab, your healthcare provider will do blood tests to check for hepatitis B viral infection. If you have ever had hepatitis B virus infection, the hepatitis B virus may become active again during or after treatment with OCREVUS ZUNOVO. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop receiving OCREVUS ZUNOVO.
- **Weakened immune system:** OCREVUS ZUNOVO taken before or after other medicines that weaken the immune system could increase your risk of getting infections.
- **Progressive Multifocal Leukoencephalopathy (PML):** PML is a rare brain infection that usually leads to death or severe disability, and has been reported with ocrelizumab. Symptoms of PML get worse over days to weeks. It is important that you call your healthcare provider right away if you have any new or worsening neurologic signs or symptoms that have lasted several days, including problems with:
 - thinking
 - eyesight
 - strength
 - balance
 - weakness on 1 side of your body
 - using your arms or legs
- **Decreased immunoglobulins:** OCREVUS ZUNOVO may cause a decrease in some types of immunoglobulins. Your healthcare provider will do blood tests to check your blood immunoglobulin levels.

See “**What are the possible side effects of OCREVUS ZUNOVO?**” for more information about side effects.

What is OCREVUS ZUNOVO?

OCREVUS ZUNOVO is a prescription medicine used to treat:

- relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- primary progressive MS, in adults.

It is not known if OCREVUS ZUNOVO is safe and effective in children.

Who should not receive OCREVUS ZUNOVO?

Do not receive OCREVUS ZUNOVO if you:

- have an active hepatitis B virus (HBV) infection.
- have had a life-threatening administration reaction to ocrelizumab.
- have had a life-threatening allergic reaction to ocrelizumab, hyaluronidase, or any of the ingredients of OCREVUS ZUNOVO. Tell your healthcare provider if you have had an allergic reaction to OCREVUS ZUNOVO or any of its ingredients in the past. See **“What are the ingredients in OCREVUS ZUNOVO?”** for a complete list of ingredients in OCREVUS ZUNOVO.

Before receiving OCREVUS ZUNOVO, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection. See **“What is the most important information I should know about OCREVUS ZUNOVO?”**
- have ever taken, take, or plan to take medicines that affect your immune system, or other treatments for MS. These medicines could increase your risk of getting an infection.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have a history of inflammatory bowel disease or colitis.
- have had a recent vaccination or are scheduled to receive any vaccinations.
 - **You should receive any required ‘live’ or ‘live-attenuated’ vaccines at least 4 weeks before you start treatment with OCREVUS ZUNOVO.** You **should not receive** ‘live’ or ‘live-attenuated’ vaccines while you are being treated with OCREVUS ZUNOVO and until your healthcare provider tells you that your immune system is no longer weakened.
 - **When possible, you should receive any ‘non-live’ vaccines at least 2 weeks before you start treatment with OCREVUS ZUNOVO.** If you would like to receive any non-live (inactivated) vaccines, including the seasonal flu vaccine, while you are being treated with OCREVUS ZUNOVO, talk to your healthcare provider.
 - If you have a baby and you received OCREVUS ZUNOVO during your pregnancy, it is important to tell your baby’s healthcare provider about receiving OCREVUS ZUNOVO so they can decide when your baby should be vaccinated.
- are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if OCREVUS ZUNOVO will harm your unborn baby. You should use birth control (contraception) during treatment with OCREVUS ZUNOVO and for 6 months after your last injection of OCREVUS ZUNOVO. Talk with your healthcare provider about what birth control method is right for you during this time. Tell your healthcare provider if you become pregnant while receiving OCREVUS ZUNOVO.
- are breastfeeding or plan to breastfeed. It is not known if OCREVUS ZUNOVO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take OCREVUS ZUNOVO.

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

How will I receive OCREVUS ZUNOVO?

- OCREVUS ZUNOVO should be administered by a healthcare professional.
- OCREVUS ZUNOVO is given through an injection (subcutaneous injection) in your stomach.
- Before treatment with OCREVUS ZUNOVO, your healthcare provider will give you a corticosteroid medicine and an antihistamine to help reduce injection reactions (make them less frequent and less severe). You may also receive other medicines to help reduce injection reactions. See **“What is the most important information I should know about OCREVUS ZUNOVO?”**
- Each injection will last about 10 minutes and will be given every 6 months.

What are the possible side effects of OCREVUS ZUNOVO?**OCREVUS ZUNOVO may cause serious side effects, including:**

- see “**What is the most important information I should know about OCREVUS ZUNOVO?**”
- **Risk of cancers (malignancies) including breast cancer:** Follow your healthcare provider’s instructions about standard screening guidelines for breast cancer.
- **Inflammation of the colon, or colitis:** Tell your healthcare provider if you have any symptoms of colitis, such as:
 - Diarrhea (loose stools) or more frequent bowel movements than usual
 - Stools that are black, tarry, sticky or have blood or mucus
 - Severe stomach-area (abdomen) pain or tenderness

The most common side effects of OCREVUS ZUNOVO include:

- injection reactions
- respiratory tract infections
- skin infections

These are not all the possible side effects of OCREVUS ZUNOVO.

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 OCREVUS ZUNOVO.

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 OCREVUS ZUNOVO that is written for health professionals.

What are the ingredients in OCREVUS ZUNOVO?

Active ingredient: ocrelizumab and hyaluronidase-ocsq.

Inactive ingredients: glacial acetic acid, methionine, polysorbate 20, sodium acetate, trehalose, and water for injection.

Manufactured by: Genentech, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990

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For more information, go to www.OCREVUS.com or call 1-844-627-3887.

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

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