Problematic side effects of OCREVUS include:

- **Infusion reactions:** Occur most often during or 24 hours after treatment. Symptoms may include:
  - Itchy skin
  - Trouble breathing
  - Nausea
  - Shortness of breath
  - Rash
  - Headache
  - Fatigue
  - Hives
  - Feeling faint
  - Swelling of the throat
  - Fast heart beat
  - Stomach ache
  - Rash on face (flushing)
  - Wheezing
  - Fever
  - Dizziness
  - Coughing or wheezing
  - Redness on face

- **Infection:** Risk of getting infections increases with OCREVUS treatment. Symptoms may include:
  - Cold sores
  - Genital sores
  - Pain
  - Shingles
  - Skin rash
  - Itching
  - Changes in vision
  - Severe or persistent headache
  - Confusion
  - Eye redness or eye pain
  - Stiff neck
  - Weakness on 1 side of your body
  - Balance
  - Weakness on 1 side of your body
  - Using your arms or legs

- **Hepatitis B virus (HBV) reactivation:** Risk of hepatitis B virus becoming active again while receiving OCREVUS.
- **Weakened immune system:** Risk of getting more infections while taking OCREVUS.
- **Progressive Multifocal Leuкоencephalopathy (PML):** Risk of developing brain infections.
- **Decreased immunoglobulins:** Risk of reduced immune function.

Before starting OCREVUS treatment, consult with a healthcare provider to discuss potential risks and benefits.

See “What is OCREVUS?” for more information about possible side effects.
- Do not receive OCREVUS if you have an active hepatitis B virus (HBV) infection.
- Do not receive OCREVUS if you have had a life-threatening allergic reaction to OCREVUS. Tell your healthcare provider if you have had an allergic reaction to OCREVUS or any of its ingredients in the past. See “What are the ingredients in OCREVUS?” for a complete list of ingredients in OCREVUS.

Before receiving OCREVUS, 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?”
- 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. You should not receive ‘live’ or ‘live-attenuated’ vaccines while you are being treated with OCREVUS 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. If you would like to receive any non-live (inactivated) vaccines, including the seasonal flu vaccine, while you are being treated with OCREVUS, talk to your healthcare provider.
  - If you have a baby and you received OCREVUS during your pregnancy, it is important to tell your baby’s healthcare provider about receiving OCREVUS 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 will harm your unborn baby. You should use birth control (contraception) during treatment with OCREVUS and for 6 months after your last infusion of OCREVUS. 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.
- are breastfeeding or plan to breastfeed. It is not known if OCREVUS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take OCREVUS.

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?
- OCREVUS is given through a needle placed in your vein (intravenous infusion) in your arm.
- Before treatment with OCREVUS, your healthcare provider will give you a corticosteroid medicine and an antihistamine to help reduce infusion reactions (make them less frequent and less severe). You may also receive other medicines to help reduce infusion reactions. See “What is the most important information I should know about OCREVUS?”
- Your first full dose of OCREVUS will be given as 2 separate infusions, 2 weeks apart. Each infusion will last about 2 hours and 30 minutes.
- Your next doses of OCREVUS will be given as 1 infusion every 6 months. These infusions will last about 2 hours to 3 hours and 30 minutes depending on the infusion rate prescribed by your healthcare provider.

What are the possible side effects of OCREVUS?
OCREVUS may cause serious side effects, including:
- see “What is the most important information I should know about OCREVUS?”
- 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

These are not all the possible side effects of OCREVUS.
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.
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 that is written for health professionals.

What are the ingredients in OCREVUS?
Active ingredient: ocrelizumab.
Inactive ingredients: glacial acetic acid, polysorbate 20, sodium acetate trihydrate, trehalose dihydrate.

Manufactured by: Genentech, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No. 1048
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

Revised: 6/2024