

Ofatumumab (Arzerra®)

Pronounce: OH-fa-TUE-mue-mab

Classification: Monoclonal Antibody

About Ofatumumab (Arzerra®)

Monoclonal antibodies are created in a lab to attach to the targets found on specific types of cancer cells. The antibody "calls" the immune system to attack the cell it is attached to, resulting in the immune system killing the cell. These antibodies can work in different ways, including stimulating the immune system to kill the cell, blocking cell growth, or other functions necessary for cell growth. Ofatumumab is directed against a protein called CD20, found on the surface of normal and cancerous B-cells, which are part of the immune system. More than 90% of CLL cases affect the B cells, making this a good target for therapy.

How to Take Ofatumumab

Ofatumumab is given by intravenous (IV, into a vein) infusion. You will receive premedication with oral steroids, acetaminophen, and anti-histamine to prevent an infusion reaction.

You, or anyone you live with, should avoid having live or live-attenuated vaccines while receiving this medication. These include herpes zoster (Zostavax) for shingles prevention, oral polio, measles, nasal flu vaccine (FluMist®), rotovirus and yellow fever vaccines.

Possible Side Effects of Ofatumumab

There are a number of things you can do to manage the side effects of ofatumumab. Talk to your doctor or nurse about these recommendations. They can help you decide what will work best for you. These are some of the most common side effects:

Liver Toxicity and Hepatitis B Reactivation

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity. This medication can also cause Hepatitis B reactivation in patients who have previously had hepatitis. Be sure your healthcare provider is aware of previous Hepatitis B diagnosis and treatment. You will also be tested for the Hepatitis B virus prior to beginning treatment with ofatumumab.

Progressive Multifocal Leukoencephalopathy (PML)

This is a rare, but very serious, brain infection that has been reported with this medication. The signs of PML may develop over several weeks or months. They may include changes in mood or usual behavior, confusion, thinking problems, loss of memory, changes in vision, speech, or walking, and decreased strength or weakness on one side of the body. If you develop any of these signs, notify your oncology care team immediately.

Infusion Related Side Effects

Almost half of the people who receive ofatumumab experience an infusion reaction. Symptoms of an infusion reaction include: fever, chills, low blood pressure, shortness of breath, flushing, swelling of the throat or face,

abdominal or back pain, rash, and itching. You will receive several medications prior to the infusion to help prevent these reactions. Reactions are most common during the first 2 infusions. Tell your infusion nurse immediately if you notice any of these symptoms, as they may need to slow or stop the infusion.

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication can cause life-threatening infections, with or without a decrease in white blood cell counts. White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as
 Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of
 bleeding. Please consult with your healthcare team regarding use of these agents and all over the
 counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Important but Less Common Side Effects

• *Tumor Lysis Syndrome (TLS):* If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea, or become lethargic (drowsy, sluggish),

notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should consult with your healthcare team before breastfeeding while receiving this medication.

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