TITLE - OFATUMUMAB / ARZERRA MEDICATION PATIENT INFORMATION IN ENGLISH

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Ofatumumab Injection (Chronic Lymphocytic Leukemia)

pronounced as (o" fa toom' ue mab)

Notice:

Ofatumumab injection (Arzerra) is only available though a special restricted distribution program (Arzerra Oncology Access Program). In order to receive ofatumumab injection (Arzerra) your doctor must be registered with the program, and follow the requirements. The Arzerra Oncology Access Program will ship the medication directly to the doctor, hospital, or pharmacy.

IMPORTANT WARNING:

You may already be infected with hepatitis B (a virus that infects the liver and may cause severe liver damage) but not have any symptoms of the disease. In this case, ofatumumab injection may increase the risk that your infection will become more serious or life-threatening and you will develop symptoms. Tell your doctor if you have or ever had hepatitis B virus infection. Your doctor will order a blood test to see if you have an inactive hepatitis B virus infection. If necessary, your doctor may give you medication to treat this infection before and during your treatment with ofatumumab. Your doctor will also monitor you for signs of hepatitis B infection during and for several months after your treatment. If you experience any of the following symptoms during or after your treatment, call your doctor immediately: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea or vomiting, muscle aches, stomach pain, or dark urine.

Some people who received ofatumumab developed progressive multifocal leukoencephalopathy (PML; a rare infection of the brain that cannot be treated, prevented, or cured and that usually causes death or severe disability) during or after their treatment. If you experience any of the following symptoms, call your doctor immediately: new or sudden changes in thinking or confusion, dizziness, loss of balance, difficulty talking or walking, new or sudden changes in vision, or any other unusual symptoms that develop suddenly.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to ofatumumab injection.

Talk to your doctor about the risks of using ofatumumab injection.

Why is this medication prescribed?

Ofatumumab injection is used to treat chronic lymphocytic leukemia (CLL; a type of cancer of the white blood cells):

- in combination with chlorambucil in people who have not received treatment or are unable to receive treatment with fludarabine (Fludara).
- in combination with fludarabine (Fludara) and alemtuzumab (Campath) when CLL has returned after previous treatment.
- as extended treatment in people with CLL that has improved fully or partially after at least two lines of treatment.
- in people who have not responded to treatment with fludarabine (Fludara) and alemtuzumab (Campath).

Ofatumumab injection is in a class of medications called monoclonal antibodies. It works by killing cancer cells.

Ofatumumab is also available as an injection (Kesimpta) that is used to treat multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control). This monograph only gives information about ofatumumab injection (Arzerra) for treatment of chronic lymphocytic leukemia. If you are receiving ofatumumab for multiple sclerosis, read the monograph entitled Ofatumumab Injection (Multiple Sclerosis).

How should this medicine be used?

Ofatumumab injection comes as a solution (liquid) to be added to fluid and injected intravenously (into a vein) by a doctor or nurse in a medical office or hospital. It is usually injected once a week. The length of your treatment depends on your condition and on how well you respond to treatment.

You may experience a reaction during or for up to 24 hours after you receive a dose of ofatumumab. Your doctor will give you other medications to prevent or treat certain side effects 30 minutes to 2 hours before you receive each dose of ofatumumab injection. Tell your doctor immediately if you experience any of these symptoms while you receive ofatumumab: fever, chills, rash, or difficulty breathing. Be sure to tell your doctor how you are feeling during your treatment with ofatumumab injection.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving ofatumumab injection,

- tell your doctor and pharmacist if you are allergic to ofatumumab, any other medications, or any of the ingredients in ofatumumab injection. Ask your pharmacist for a list of the ingredients.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had chronic obstructive pulmonary disease (COPD; a group of diseases that affect the lungs and airways)
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while receiving ofatumumab injection, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are receiving ofatumumab injection.
- ask your doctor whether you should receive any vaccinations before you begin your treatment with ofatumumab. Do not have any vaccinations during your treatment without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Ofatumumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- muscle spasms
- stuffy or runny nose
- diarrhea
- headache
- difficulty sleeping

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section , call your doctor immediately:

- difficulty breathing or swallowing
- heavy sweating
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- sudden reddening of the face, neck, or upper chest
- weakness
- unusual bleeding or bruising
- pale skin
- pinpoint, flat, round, red spots under the skin
- rash
- hives

- fever, chills, cough, sore throat, or other signs of infection
- pain in arms, back, neck, or jaw
- chest pain,
- fast heartbeat
- fainting

Ofatumumab injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch [http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at https://www.poisonhelp.org/help [https://www.poisonhelp.org/help] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Ask your pharmacist any questions you have about ofatumumab injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Arzerra ®

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