Approved Use
ARZERRA is a prescription medication used:

• With a chemotherapy drug called chlorambucil to treat chronic lymphocytic leukemia (CLL) in adults who have not had previous CLL treatment and whose doctor had decided not to treat them with a chemotherapy drug called fludarabine

• With fludarabine and a chemotherapy drug called cyclophosphamide for patients whose CLL has relapsed (come back)

• Alone for continued follow-up treatment of patients whose extent of cancer has decreased (partial response) or whose signs of cancer have completely disappeared (complete response) after being treated with at least two lines of therapy for their recurrent or progressive CLL

• Alone to treat patients with CLL whose disease has stopped responding (refractory) to treatment with fludarabine and a monoclonal antibody called alemtuzumab

IMPORTANT SAFETY INFORMATION ABOUT ARZERRA® (ofatumumab)

• Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening

• Treatment with ARZERRA may cause hepatitis B virus (HBV) infection to reoccur, which may cause serious liver problems and death. Tell your doctor if you had HBV infection or are a carrier of HBV

• Progressive multifocal leukoencephalopathy (PML) is a rare brain infection that can occur with treatment with ARZERRA. PML causes severe disability and can lead to death

Please see additional Important Safety Information for ARZERRA on pages 14-16.
Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
Be in the Know
About ARZERRA® (ofatumumab)

Now that you’re starting treatment with ARZERRA, you may have questions. This booklet is designed to help you feel more informed and involved in your treatment with ARZERRA. This information does not replace speaking with your health care provider. You should always contact your health care provider if you have questions about your condition and treatment.

ARZERRA is a prescription medicine called a monoclonal antibody. It is approved for:

- Patients who have CLL and have not been treated before, and whose doctor has decided not to treat them with a chemotherapy drug called fludarabine. ARZERRA is given with chlorambucil, a type of medicine called an alkylator chemotherapy
- Patients whose cancer has relapsed, or come back after treatment and reaching remission, with fludarabine and a chemotherapy drug called cyclophosphamide
- The continued follow-up treatment of patients who are in complete response (whose signs of cancer have disappeared) or partial response (whose extent of cancer has decreased) after being treated with at least two lines of therapy for their recurrent or progressive CLL
- Patients whose CLL is refractory (stopped responding) to treatment with fludarabine and alemtuzumab

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
Be in the Know About ARZERRA® (ofatumumab) (cont)

You’ve been given ARZERRA

Your health care provider has prescribed ARZERRA to treat your CLL. In order to get the most out of therapy, it’s important that you know about ARZERRA and what to expect from treatment.

Treatment approaches

• If you have not been previously treated for CLL, you may live for years without treatment, but you may need to be treated if your disease progresses or if you have bothersome symptoms. Your doctor will discuss with you which treatment option may benefit you based on your age, general health, history, and conditions.

• If you have received previous therapy and your CLL has relapsed, or come back after treatment and reaching remission, your doctor may prescribe different treatment regimens than the ones you received initially. If your response to the first treatment lasted at least a few years, your doctor may decide to use the same treatment again.

• If you have responded to previous therapy (some or all of the signs and symptoms of your cancer have disappeared, although cancer may still be in your body), your doctor may decide to give you continued follow-up therapy to slow the progression of your disease.

• If you have received previous therapy and your disease stopped responding to treatment, your doctor may prescribe different treatment regimens than the ones you received initially.

The following pages will help you understand:

• How ARZERRA is given

• The dosing schedule for ARZERRA

• What side effects you may have

This brochure may also help to answer other questions you have about ARZERRA. But remember, you should always discuss any questions about your treatment with your health care provider.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
How ARZERRA® (ofatumumab) Is Given

ARZERRA is given by intravenous (IV) infusion; that is, through a needle placed in a vein in your arm. Before the treatment, you will be given 3 medicines to help decrease the chance of a possible reaction to the infusion. These medicines are a pain reliever, an antihistamine to reduce allergic reactions, and a steroid to reduce swelling and other symptoms of inflammation. Your health care provider will tell you where you will receive the treatment—for example, a hospital, clinic, or treatment facility.

How often ARZERRA is given

Treatment with ARZERRA is scheduled as follows, based on your condition:

- **If you have not been previously treated for CLL:** Your treatment will be scheduled in 28-day cycles. You will receive 2 infusions during the first cycle (300 mg on Day 1 and 1000 mg on Day 8). On Day 1 of the following cycles, you will receive a 1000-mg infusion for at least 3 cycles, until best response, or as many as 12 cycles. Your doctor will decide the number of treatment cycles you’ll receive, depending on how your CLL responds to the treatment.

- **If you have received previous therapy and your CLL has relapsed, or come back after treatment and reaching remission:** Your treatment will be scheduled in 28-day cycles. You will receive 2 infusions during the first cycle (300 mg on Day 1 and 1000 mg on Day 8). On Day 1 of the following cycles, you will receive a 1000-mg infusion for as many as 6 cycles. Your doctor will decide the number of treatment cycles you’ll receive, depending on how your CLL responds to the treatment.

- **If you are to receive continued follow-up treatment with ARZERRA:** You will receive 300 mg on Day 1 and 1000 mg on Day 8. You will then receive 1000 mg 7 weeks later and every 8 weeks for a maximum of 2 years. Your doctor will decide the number of treatment cycles you’ll receive, depending on how your CLL responds to the treatment.

- **If your CLL is refractory to fludarabine and alemtuzumab:** You will receive 300 mg on Day 1, then 1 week later, you will receive 2000 mg weekly for 7 doses. Four weeks later, you will receive 2000 mg every 4 weeks for 4 doses.

How long is each infusion of ARZERRA?

Your first infusion of ARZERRA may last 5 hours or longer. The rest of your infusions may take 4 to 4½ hours. Your health care provider will watch you carefully to see how your body reacts to ARZERRA. That will help him or her know how slowly you should receive your infusion. How long your entire treatment visit may take will depend on how your body reacts to the infusion.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16. Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
How ARZERRA® (ofatumumab) Is Given (cont)

Infusion schedule for ARZERRA and chlorambucil

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This is an example of an infusion schedule. Your health care provider will decide what infusion schedule is right for you.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.
Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
How ARZERRA® (ofatumumab) Is Given (cont)

Infusion schedule for ARZERRA plus fludarabine and cyclophosphamide

This is an example of an infusion schedule. Your health care provider will decide what infusion schedule is right for you.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening.

Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
How ARZERRA® (ofatumumab) Is Given (cont)

Infusion schedule for continued follow-up treatment with ARZERRA

This is an example of an infusion schedule. Your health care provider will decide what infusion schedule is right for you.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
**How ARZERRA® (ofatumumab) Is Given (cont)**

Infusion schedule for CLL refractory to fludarabine and alemtuzumab

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Dose 1 (on Day 1)

Weekly doses (for 7 weeks)

No dose (for 4 weeks)

Subsequent doses

This is an example of an infusion schedule. Your health care provider will decide what infusion schedule is right for you.

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**SAFETY**

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including **Boxed WARNING**, for ARZERRA.
Possible Side Effects
With ARZERRA® (ofatumumab)

- Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening.
- Treatment with ARZERRA may cause hepatitis B virus (HBV) infection to reoccur, which may cause serious liver problems and death. Tell your doctor if you had HBV infection or are a carrier of HBV.
- Progressive multifocal leukoencephalopathy (PML) is a rare brain infection that can occur with treatment with ARZERRA. PML causes severe disability and can lead to death.

Infusion reactions

Treatment with ARZERRA may cause a side effect called an infusion reaction, which may be serious and may even lead to death in some people. Your doctor or nurse will stop your treatment so the infusion reaction can be treated. If you experience severe allergic reactions (anaphylaxis), your infusion will be stopped and you will not continue treatment with ARZERRA. If a reaction occurs, it is most likely to happen with the first 2 infusions and less likely with later infusions. Signs and symptoms of infusion reactions may include:

- Fever
- Chills
- Rash
- Hives
- Chest pain
- Back pain
- Stomach pain
- Swelling
- Dizziness
- Blurred vision
- Drowsiness
- Headache
- Cough
- Wheezing
- Trouble breathing

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16. Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
Possible Side Effects
With ARZERRA® (ofatumumab) (cont)

Be sure to tell your health care provider or seek medical treatment right away if you have any of these symptoms while receiving, or within 24 hours after receiving, ARZERRA.

To help decrease the chance of a possible infusion reaction, your health care provider will give you 3 types of medicines before your treatment. These medicines are a pain reliever, an antihistamine to reduce allergic reactions, and a steroid to reduce swelling and other symptoms of inflammation. Even though you will receive these medicines, you may still have an infusion reaction.

Remember, your doctor and nurse(s) are trained to handle infusion reactions. If you feel anything unusual during or after your infusion, be sure to mention it right away. If you have an unusual reaction after you leave the infusion facility, call your doctor’s office immediately.

Most common side effects with ARZERRA:

- Infusion reactions
- Low white blood cell count
- Pneumonia
- Fever
- Cough
- Diarrhea
- Low red blood cell count
- Feeling tired
- Shortness of breath
- Rash
- Nausea
- Bronchitis
- Upper respiratory tract infection

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
Possible Side Effects
With ARZERRA® (ofatumumab) (cont)

Tell your health care provider right away if you have any of the following serious side effects during or after treatment:

- Fever
- Chills
- Rash
- Cough
- Breathing problems
- Bleeding
- Bruise easily
- Small red or purple spots on the skin
- Pale skin
- Yellow-colored skin or eyes
- Feeling tiredness or weakness that is worse than before
- Confusion
- Dizziness or loss of balance
- Trouble talking
- Trouble walking
- Vision problems
- New or worsening abdominal pain or nausea
- Generally feeling much sicker than before

Other serious side effects
Use of ARZERRA may cause:

- **Hepatitis B virus** reactivation or infection
- **Progressive multifocal leukoencephalopathy**, a potentially deadly brain disease
- **Tumor lysis syndrome**, a complication from cancer treatment that may cause damage to certain organs of the body, such as the heart and kidneys
- **Cytopenias**, conditions that reduce the creation of blood cells

These are not all of the possible side effects of ARZERRA. Tell your health care provider about any side effects you experience.
Questions You May Have About ARZERRA® (ofatumumab)

What should I tell my health care provider before starting treatment?

Before starting treatment, be sure to tell your health care provider if you:

• Have an infection or have an infection that will not go away or that keeps coming back
• Have or have had hepatitis (liver) infection
• Are scheduled to receive any vaccinations. After you receive ARZERRA, you should not receive live vaccines until the health care provider who prescribed ARZERRA has told you that you may do so
• Are pregnant or are planning to become pregnant. It is not known if ARZERRA can harm your unborn baby
• Are breast-feeding. It is not known if ARZERRA passes into human breast milk. You should not breast-feed while being treated with ARZERRA

In addition, tell your health care provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

What is an infusion reaction?

In some cases, your body may react to an infusion. For more information on the signs and symptoms of an infusion reaction, please see page 9. Contact your health care provider if you think you are having an infusion reaction.

SAFETY

Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.

Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
Questions You May Have About ARZERRA® (ofatumumab) (cont)

What are the ingredients in ARZERRA?
The active ingredient is ofatumumab. The inactive ingredients are arginine, diluted hydrochloric acid, edetate disodium, polysorbate 80, sodium acetate, sodium chloride, and water for injection. If you are allergic to any of these ingredients, tell your health care provider. ARZERRA is provided in a single-use glass vial with a rubber stopper (not made with natural rubber latex) and an aluminum overseal.

Patient Assistance Now Oncology (PANO)
Novartis Oncology is committed to helping patients living with cancer receive the medicines they need. Patient Assistance Now Oncology (PANO) offers quick and easy access to information about our wide range of resources.
You can get information about our PANO support program by calling 1-800-282-7630 to speak with a member of our knowledgeable staff dedicated to making access to therapy as simple and convenient as possible.

SAFETY
Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening. Please see additional Important Safety Information for ARZERRA on pages 14-16.
Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.
ARZERRA® (ofatumumab) Indications

ARZERRA is a prescription medication used:

- With a chemotherapy drug called chlorambucil to treat chronic lymphocytic leukemia (CLL) in adults who have not had previous CLL treatment and whose doctor has decided not to treat them with a chemotherapy drug called fludarabine
- With fludarabine and a chemotherapy drug called cyclophosphamide for patients whose CLL has relapsed (come back)
- Alone for continued follow-up treatment of patients whose extent of cancer has decreased (partial response) or whose signs of cancer have completely disappeared (complete response) after being treated with at least two lines of therapy for their recurrent or progressive CLL
- Alone to treat patients with CLL whose disease has stopped responding (refractory) to treatment with fludarabine and a monoclonal antibody called alemtuzumab

IMPORTANT SAFETY INFORMATION ABOUT ARZERRA® (ofatumumab)

- Treatment with ARZERRA may cause side effects, some of which are serious and life-threatening
- Treatment with ARZERRA may cause hepatitis B virus (HBV) infection to reoccur, which may cause serious liver problems and death. Tell your doctor if you had HBV infection or are a carrier of HBV
- Progressive multifocal leukoencephalopathy (PML) is a rare brain infection that can occur with treatment with ARZERRA. PML causes severe disability and can lead to death

Infusion Reactions

- Treatment with ARZERRA may cause a side effect called an infusion reaction, which may be serious and may lead to death in some people
- Before your treatment with ARZERRA, your doctor or nurse will give you 3 types of medicines to help reduce the risk of an infusion reaction. If you experience an infusion reaction, your doctor or nurse will stop your treatment so the infusion reaction can be treated
- If you experience severe allergic reactions (anaphylaxis), your infusion will be stopped and you will not continue treatment with ARZERRA

Be sure to tell your doctor or nurse or seek medical treatment right away if you experience any of the following symptoms while receiving or within 24 hours after receiving ARZERRA: Fever, chills, rash, hives, chest pain, back pain, stomach pain, swelling, dizziness, blurred vision, drowsiness, headache, cough, wheezing, or trouble breathing.
IMPORTANT SAFETY INFORMATION ABOUT ARZERRA® (ofatumumab) (cont)

Hepatitis B

- Tell your doctor if you had hepatitis B virus (HBV) infection or are a carrier of HBV
- Treatment with ARZERRA may cause the HBV to become an active infection. This may cause serious liver problems and death. People with active liver disease due to HBV should not receive ARZERRA
- If you are newly exposed to HBV during or following treatment with ARZERRA, you may experience serious liver problems and death
- Your doctor will perform a blood test to check for HBV infection before starting treatment with ARZERRA. If you had HBV infection or are a carrier of HBV, your doctor will keep checking you during and several months after ARZERRA treatment to see if the HBV becomes an active infection. In some people, HBV became an active infection at least 12 months after treatment with ARZERRA
- Call your doctor right away if you feel more tired than usual or notice a yellowing of your skin or eyes. These may be symptoms of HBV

Progressive Multifocal Leukoencephalopathy

- Progressive multifocal leukoencephalopathy (PML) is a rare brain infection. It is a serious side effect that may happen with treatment. PML causes severe disability and may lead to death
- Call your doctor right away if you notice new medical problems or problems that are getting worse, such as confusion, dizziness or loss of balance, difficulty talking or walking, or strength, vision, or other problems that have lasted over several days
- There is no known treatment, prevention, or cure for PML

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including the need for a hospital stay, may occur with treatment with ARZERRA
- TLS is caused by the breakdown of cancer cells, which then release their contents into the blood. This may lead to damage of certain organs, such as the heart and kidneys
- Your doctor may do a blood test to check you for TLS and may give you medicines before your treatment to help prevent TLS

Low Blood Cell Counts

- ARZERRA may cause low blood cell counts (white blood cells, platelets, and red blood cells). These low blood cell counts may be severe and, in some cases, lead to death. Low white blood cell count, also called neutropenia, may happen during treatment or even weeks later. Your doctor will check your blood to see if you have low blood cell counts and need to be treated for them
- Call your doctor right away if you have any bleeding, bruising, red or purple spots on your body, paleness, worsening weakness, tiredness, cough that will not go away, fever, chills, congestion, or any flu-like symptoms while receiving ARZERRA
IMPORTANT SAFETY INFORMATION ABOUT ARZERRA® (ofatumumab) (cont)

**Common Side Effects With ARZERRA**

- Infusion reactions
- Low white blood cell count
- Pneumonia
- Fever
- Cough
- Diarrhea
- Low red blood cell count
- Feeling tired
- Shortness of breath
- Rash
- Nausea
- Bronchitis
- Upper respiratory tract infections

**Infections**

- ARZERRA may increase your chances for developing infections. Some infections, such as pneumonia, bronchitis, and sepsis (a blood infection), may be serious, and in some cases, life-threatening.
- Call your doctor right away if you have a cough that will not go away, fever, chills, congestion, or any flu-like symptoms while receiving ARZERRA. These symptoms may be signs of a serious infection.

**Immunizations**

- Avoid receiving a type of vaccination called a live viral vaccine while being treated with ARZERRA.
ARZERRA® (ofatumumab) is a prescription medicine. You are encouraged to report negative side effects of prescription drugs to the US Food and Drug Administration (FDA). Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

SAFETY

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Please click here for full Prescribing Information, including Boxed WARNING, for ARZERRA.

All photos are for illustrative purposes only and do not depict actual patients.