PART III: CONSUMER INFORMATION

PrARZERRA™
(ofatumumab)

This leaflet is part III of a three-part "Product Monograph" published when ARZERRA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ARZERRA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ARZERRA (R-ZEER-ah) contains ofatumumab, which belongs to a group of medicines called monoclonal antibodies.

ARZERRA is used to treat chronic lymphocytic leukaemia (CLL). CLL is a cancer of the blood that affects a type of white blood cell called lymphocytes. The lymphocytes multiply too quickly and live too long, so there are too many of them circulating in your blood. The disease can also affect other organs in your body. The antibody in ARZERRA binds to the lymphocytes and decreases the amount of lymphocytes in the body.

What it does:

ARZERRA is used in combination with chlorambucil to treat CLL in patients who have not received previous therapy.

ARZERRA is also used as monotherapy to treat CLL in patients who have not responded to other types of chemotherapy or other treatments.

When it should not be used:

- If you have or have had progressive multifocal leukoencephalopathy (PML).
- If you are allergic (hypersensitive) to ofatumumab or to any of the other nonmedicinal ingredients of ARZERRA.

Check with your doctor if you think this may apply to you.

What the medicinal ingredient is:

The active substance in ARZERRA is ofatumumab.

What the important nonmedicinal ingredients are:

Inactive ingredients include: 10 mg/mL arginine, diluted hydrochloric acid, 0.019 mg/mL edetate disodium, 0.2 mg/mL polysorbate 80, 6.8 mg/mL sodium acetate, 2.98 mg/mL sodium chloride, and Water for Injection, USP. The pH is 5.5.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

ARZERRA is a clear to opalescent, colourless to pale yellow concentrate solution for infusion.

It is available in a pack containing 3x5 mL vials or 1x50 mL vial. Each glass vial is closed with a latex-free rubber stopper and aluminium over-seal, and contains 100 mg/1,000 mg of ofatumumab per 5 mL/50 mL of concentrate respectively.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- ARZERRA administration could result in serious, including fatal infusion-related reactions.
- ARZERRA administration could result in hepatitis (a liver disease) becoming active again. In some cases, this could result in liver failure and even death.
- Administration of ARZERRA and other similar medicines could result in a serious and fatal brain condition called progressive multifocal leukoencephalopathy (PML).
- ARZERRA administration could result in serious and/or fatal cardiovascular events.
- ARZERRA administration could result in serious and sometimes fatal infections.

BEFORE you use ARZERRA, talk to your doctor or pharmacist if:

- you have had heart problems.
- you have lung disease.
- you have had hepatitis B (a liver disease). ARZERRA administration could result in your hepatitis B becoming active again. Your doctor may treat you with a suitable anti-viral medicine to help prevent this.
- you are allergic (hypersensitive) to ofatumumab or to any of the other nonmedicinal ingredients of ARZERRA.
- you have had a reaction to an injectable medication in the past.

Check with your doctor if you think any of these may apply to you. You may need extra check-ups while you are being treated with ARZERRA.

Vaccination and ARZERRA
If you are having any vaccinations tell your doctor, or the person giving you the vaccine, that you are being treated with ARZERRA. Your response to the vaccine may be weakened and you may not be fully protected.

Infusion-related reactions
Medicines of this type (monoclonal antibodies) can cause infusion-related reactions when they are injected into your body, which are occasionally severe, and can cause death. You will be given medicines such as anti-histamines, steroids or pain relievers to help reduce any reaction. See SIDE EFFECTS AND WHAT TO DO ABOUT THEM, section.

Hepatitis B
Recurrence of hepatitis B virus infection has occurred in patients who show evidence of the virus in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with ARZERRA.

In some cases, patients who have had hepatitis B might have a repeat attack of hepatitis. Tell your doctor if you think you have had hepatitis in the past.

Infection with hepatitis B virus causes inflammation of the liver which may show as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue. If you experience any of these symptoms immediately contact your doctor. If you show evidence of hepatitis B virus infection (even if you have no symptoms) you may be referred to a liver disease expert for ongoing monitoring and management.

ARZERRA is not to be used in patients with active hepatitis B viral disease. Tell your doctor if you think you have hepatitis B.

Progressive multifocal leukoencephalopathy (PML)
ARZERRA and other similar medicines may cause a serious and life threatening brain condition called progressive multifocal leukoencephalopathy (PML). **Tell your doctor immediately** if you have memory loss, trouble with thinking, difficulty with walking or loss of vision. If you had these symptoms prior to treatment with ARZERRA, **tell your doctor immediately** about any changes in these symptoms.

Tumour Lysis Syndrome (TLS)
TLS can occur with the use of ARZERRA. TLS is a condition that causes sudden kidney failure and abnormal heart rhythms due to changes in blood chemistry, which may be fatal. Some patients with TLS in its early stages have no symptoms. The symptoms of TLS include the production of less urine than normal and muscle spasms. Patients with TLS usually have a high level of potassium, phosphate and uric acid and low calcium levels in their blood. Your doctor will be performing blood tests for this and other side effects.

Infections
Patients receiving ARZERRA may develop infections. Some of the infections may be serious. Call your healthcare provider right away if you feel sick or get any of the following symptoms, which may be early signs of a serious infection:

- Fever or chills
- Difficulty breathing
- Cough
- Cold or flu-like symptoms that do not go away
- Feel weak or generally unwell

Cytopenias
A decrease in number of one or more types of blood cells (cytopenias) can occur with patients taking ARZERRA. Your doctor will be carefully monitoring the effects of treatment and your progress by examining you and by taking blood samples on a regular basis.

Bowel obstruction
Bowel problems, including blockage in the intestines (bowel obstruction) have been reported during the use of ARZERRA. If you have persistent stomach pain, see your doctor immediately.

Other medicines and ARZERRA
Tell your doctor if you are taking any other medicines, if you've taken any recently, or if you start taking any new ones. This includes herbal medicines and other medicines you can obtain without a prescription.

Pregnancy and breast-feeding
ARZERRA is not usually recommended for use during pregnancy. There is limited information about the safety of ARZERRA in pregnant women.

- Tell your doctor if you are pregnant or planning to become pregnant. Your doctor will weigh the benefit to you against the risk to your baby of taking ARZERRA while you're pregnant.
- Use a reliable method of contraception to avoid becoming pregnant while you're being treated with ARZERRA, and for at least 6 months after your last infusion with ARZERRA.
- If you do become pregnant during treatment with ARZERRA, tell your doctor.

It is not known whether the ingredients of ARZERRA can pass into human milk. If you are breast-feeding, you must check with your doctor before you take ARZERRA.

Driving and using machines
ARZERRA is unlikely to affect your ability to drive or use machines.

INTERACTIONS WITH THIS MEDICATION

No formal drug interaction studies have been conducted with ARZERRA (ofatumumab).

PROPER USE OF THIS MEDICATION

If you have any questions about how to use ARZERRA, ask the doctor who is giving you the infusion.

Usual dose:
The usual dose of ARZERRA for the first infusion is 300 mg. This dose will be increased, usually to either 1,000 mg or 2,000 mg, for the remaining infusions.

How it is given
ARZERRA is given into a vein (intravenously) as an infusion (a drip) over several hours.

You may have a course of up to 12 infusions. Depending on whether you are being treated with ARZERRA as monotherapy or in combination with chlorambucil you will be given:

- An infusion once a week for 8 weeks, followed by a four week gap. The remaining infusions will then be given once a month for four months; or
- Two infusions eight days apart, followed by a gap of approximately 3 weeks. The remaining infusions (up to 11) will then be given every 28 days.

Medicines given before each infusion
Before each infusion of ARZERRA, you will be given medicines that help to reduce infusion reactions. These may include anti-histamines, steroids and pain relievers. You will be checked closely and if you do have any reactions these will be treated.

Overdose:

No data are available regarding overdosage with ARZERRA.

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
Contact your physician immediately if you miss a dose of ARZERRA. Your physician will decide when you should receive your next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ARZERRA can cause side effects, although not everybody gets them.

Infusion-related reactions

Medicines of this type (monoclonal antibodies) can cause infusion-related reactions, which are occasionally severe, and can cause death. They are more likely during the first two infusions.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Common	Infusion-related reaction: • feeling sick (nausea) • high temperature • skin rash		✓	
Very Common	• infections of the lungs or airways (respiratory tract) such as pneumonia • infections of the ear, nose or throat		✓	
Very Common	Blood Tests: • low levels of white blood cells (neutropenia) • low levels of red blood cells (anaemia)		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and call your doctor or pharmacist**
		Only if severe	**In all cases**	
Common	Infusion-related reaction: • allergic reactions, sometimes severe with swelling of face or mouth causing difficulty in breathing (anaphylactoid reactions, including anaphylactic shock) • collapse • difficulty in breathing, shortness of breath, chest tightness, cough • low blood pressure (can cause light-headedness when you stand up) • flushing • excessive sweating • shaking or shivering • rapid heart beat • diarrhoea • back pain • high blood pressure • itchy, bumpy rash (hives) • throat pain or irritation • lack of energy • blocked nose.		✓	

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Common	• fever due to an infection and low levels of white blood cells • blood infections • urinary tract infections • shingles •cold sores • blockage in the gut (intestine), which may feel like stomach pain. If you have persistent stomach pain, see your doctor as soon as possible.		✓	
Common	Blood Tests: • low levels of platelets in the blood (cells that help blood to clot)		✓	
Uncommon	Tumour Lysis Syndrome: increase in potassium, phosphate and uric acid in the blood that can cause kidney problems Symptoms of this condition include: • producing less urine than normal • muscle spasms		✓	
Uncommon	Blood Tests: • problems with blood clotting • the bone marrow failing to produce enough red or white blood cells		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Infusion-related reaction: • Fluid in the lungs (pulmonary oedema) causing breathlessness • Slow heart beat		✓	
Rare	Infection or reactivation of Hepatitis B. Symptoms of hepatitis include worsening fatigue or yellow discolouration of the skin or eyes.		✓	

This is not a complete list of side effects. For any unexpected effects while taking ARZERRA, contact your doctor or oncology pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

Do not use ofatumumab after the expiry date which is stated on the carton and vial label. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C – 8°C).

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Store the diluted infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will dispose of any medicine that is no longer required. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca or by contacting the sponsor,

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