ARZERRA®

20 mg/mL injection concentrate vial
Ofatumumab (rmc)

Consumer Medicine Information

What is in this leaflet

Please read all 5 pages in this leaflet carefully before you start using Arzerra.

This leaflet answers some common questions about Arzerra (ofatumumab). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.
Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Arzerra against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Arzerra is used for

Arzerra 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 which affects a type of white blood cell called a 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 recognises a substance on the surface of lymphocytes and binds to them, decreasing the amount of lymphocytes in the body.

Your doctor may have prescribed Arzerra for another reason.

This medicine is available only with a doctor's prescription.

ARZERRA is not recommended for use in children and adolescents, under the age of 18 years.

Arzerra is not addictive.

Before you are given Arzerra

When you must not receive Arzerra

You must not receive Arzerra if you have ever had a:

- Severe allergic (hypersensitive) reaction to Arzerra (ofatumumab).
- An allergic reaction to any of the ingredients listed toward the end of this leaflet.
  See "Ingredients" on Page 4.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

Check with your doctor if you think that any of these reactions may apply to you.

Arzerra must not be used after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to the hospital pharmacist or pharmacist for disposal.

If you are not sure whether you should start to be given this medicine, talk to your doctor.

Tell your doctor if

Before you are given Arzerra your doctor needs to know if you have:

- Lung disease
- Had heart problems
- Ever had hepatitis B (a liver disease). Arzerra could cause your hepatitis B to become active again. Your doctor may treat you with a suitable anti-viral medicine to help prevent this.
- Ever had an Infusion reaction.
  See "Infusion reactions" on Page 2 for more information about this.
- Progressive multifocal leukoencephalopathy (PML), a rare is a disease that attacks part of your brain.
  See "Progressive multifocal leukoencephalopathy (PML)" in the following text.

Tell 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.

Infusion reactions

Medicines of this type (monoclonal antibodies) are given into a vein (intravenously) as an infusion (a drip) over several hours. These medicines can cause infusion reactions (side effects) when they are injected into your body. You will be given medicines such as anti-histamines, steroids or pain relievers to help reduce any reaction (see also 'Side effects').

Progressive multifocal leukoencephalopathy (PML)

Medicines like Arzerra may cause a serious and life threatening brain condition called progressive multifocal leukoencephalopathy (PML). This condition damages myelin, the fatty substance which protects nerves in the brain.

Tell your doctor immediately if you have any of these symptoms: 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.

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.

Taking other medicines

Tell your doctor, health care professional, or pharmacist if you are taking any other medicines, have taken any recently, or if you start new ones.
This includes herbal medicines and other medicines you've bought without a prescription. These might interact with Arzerra.

Pregnancy

Tell your doctor if you are pregnant or think you could be, before you are given Arzerra.
There is limited information about the safety of Arzerra in pregnant women. Your doctor will consider the benefit to you and the risk to your baby of taking Arzerra while you are pregnant.

Use a reliable method of contraception to prevent pregnancy while you're being treated with Arzerra, and for at least six months after your last infusion.

Breast-feeding

It is not known whether the ingredients in Arzerra pass into human breast milk.

If you are breast-feeding, you must check with your doctor before you take Arzerra.

Patients on controlled sodium diets

Arzerra contains 34.8 mg sodium in each 300 mg dose and 232 mg sodium in each 2000 mg dose.

If you are on a controlled sodium diet, you and your doctor or nurse need to take this into account.

Driving and using machines

Arzerra is unlikely to affect your ability to drive or use machines.

How Arzerra is used

Arzerra is to be administered by a physician or healthcare professional only.

Arzerra must not be mixed with, or administered with other medicinal products or intravenous solutions.

If you have any questions on the use of this product, ask the doctor, nurse, or healthcare professional who is giving Arzerra to you.

How much Arzerra will be given to you

The usual dose for the first infusion is 300 mg. This dose will usually be increased to 1000 mg or 2000 mg for the remaining infusions.

How it is given

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

If you have not been previously treated for CLL you will usually have a maximum of 13 infusions. You will be given an infusion followed by a second infusion 7 days later. The remaining infusions will then be given once a month for up to 11 months.

If you have been previously treated for CLL, you will usually have a course of 12 infusions. You will be given an infusion once a week for eight weeks. This is followed by a four- to five-week gap. The remaining

infusions will be given once a month for four months.

Pre-medications

Before each infusion of Arzerra, you will be given medicines which help to reduce any 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.

Possible side effects

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to receiving Arzerra, even if the problem is not listed below.

Like all medicines, Arzerra can cause side effects, although not everybody gets them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Infusion reactions

Medicines of this type (monoclonal antibodies) can cause infusion reactions, which are occasionally severe, and can cause death. They are more likely during the first treatment. You may also experience some of these side effects outside of the infusion time.

Very common symptoms of an infusion reaction

These symptoms may affect more than 1 in 10 people:

- Nausea (feeling sick)
- High temperature
- Skin rash
- Breathlessness
- Cough
- Diarrhoea
- Lack of energy.

Common symptoms of an infusion reaction

These symptoms may affect up to 1 in 10 people:

- Allergic reaction, sometimes severe, including:
  - Raised and itchy rash (hives)
  - Swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing and collapse
- Difficulty breathing, shortness of breath, tight chest and cough (possible symptoms of bronchospasm)
- Headache
- Flushing
- Excessive sweating
- Shaking or shivering (possible symptoms of chills)
- Back pain
- Drop in blood pressure which may make you feel dizzy or lightheaded
- Throat pain or irritation
- High blood pressure
- Rapid heart beat
- Feeling tired
- Shaking or excessive shivering
- Blocked nose
- Excessive sweating

Uncommon symptoms of an infusion reaction

These symptoms may affect up to 1 in 100 people:

- Breathlessness (possible sign of fluid in the lungs (pulmonary oedema))
- Anaphylactic reaction including anaphylactic shock, where symptoms include breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalized itching, skin reddening, facial/throat swelling, blue discolouration of the lips, tongue or skin)
- Blue discolouration of the lips and extremities (possible symptom of hypoxia) and slow heart beat.

Bowel obstruction

Contact your doctor immediately if you experience:

- constipation, a swollen abdomen, or abdominal pain.
  These may be possible symptoms of blockage in the bowel, especially during the early stages of your therapy.

Tell your doctor or a nurse giving you the infusion immediately if you get any of these symptoms.
The infusion may need to be slowed down. Your doctor may decide to stop your Arzerra treatment if these reactions are serious.

Other possible serious side effects

If you notice these symptoms, contact your doctor straight away.

Very common serious symptoms

These symptoms may affect more than 1 in 10 people:

- Frequent infections, fever, chills, sore throat or mouth ulcers due to infections, possible symptoms of low white blood cell count (neutropenia)
- Fever, coughing, difficulty breathing, wheezing, possible symptoms of infections of the lungs or airways including pneumonia)

Common serious symptoms

These symptoms may affect up to 1 in 10 people:

- Fever or, alternatively, a very low body temperature, chest pain, shortness of breath or rapid breathing, shaking, chills, confusion, dizziness, decreased urination and rapid pulse, possible symptoms of blood infection (sepsis including neutropenic sepsis and septic shock).

Uncommon serious symptoms

These symptoms may affect up to 1 in 100 people:

- Yellow skin and eyes, nausea, loss of appetite, dark urine, possible symptoms of an infection or reactivation of hepatitis B virus
- Memory loss, trouble with thinking, and difficulty with walking or loss of vision (possible symptoms of progressive multifocal leukoencephalopathy)
- Stomach pain, possible symptom of blockage in the bowel
- Producing less urine than normal and/or muscle spasms, possible symptoms of an increase in potassium, phosphate and uric acid in the blood that may cause kidney problems (tumour lysis syndrome).

Other possible side effects

Additional side effects have been observed with Arzerra. Most of these side effects are mild to moderate and will generally disappear after a few days to a week of treatment.

If you notice these symptoms, contact your doctor if this affects you severely.

Very common side effects

These may affect more than 1 in 10 people:

- Sore throat, feeling of pressure or pain in the cheeks and forehead, possible symptoms of infections of the ear, nose or throat.

Common side effects

These may affect up to 1 in 10 people:

- Shingles, cold sores, possible symptoms of viral infection that can be potentially severe (herpes viral infection)
- Difficulty and pain when passing urine, exaggerated sense of needing to urinate, possible symptoms of urinary tract infection.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if any of the side effects listed become severe or troublesome, or if you notice any side effects not listed in this leaflet.

How to store Arzerra

Arzerra Concentrate

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

Do not freeze.

Store the vial in the in the original packaging to protect from light.

Keep this medicine out of the reach and sight of children.

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

Diluted solution for infusion

Store the diluted infusion solution between 2°C and 8°C and use within 24 hours.

Do not freeze.

Discard any unused infusion solution 24 hours after it was prepared.

Product description

What Arzerra looks like

Arzerra is a colourless to pale yellow solution containing 20 mg/mL of ofatumumab.

Arzerra 100 mg
This is available in a pack containing 3 clear glass vials with a latex-free stopper and aluminium over-seal. The vial contains 5 mL of concentrate (100 mg of ofatumumab).

Arzerra 1,000 mg
This is available in a pack containing 1 clear glass vial with a latex-free stopper and aluminium over-seal. The vial contains 50 mL of concentrate (1,000 mg of ofatumumab).

Ingredients

Each mL of Arzerra contains ofatumumab 20 mg as the active ingredient. The other ingredients are:

- arginine
- disodium edetate
- hydrochloric acid (E507)
- polysorbate 80 (E433)
- sodium acetate (E262)
- sodium chloride
- water for injections.

Sponsor

Arzerra is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road, Macquarie Park NSW 2113 Australia
Telephone 1 800 671 203
www.novartis.com.au
® Registered Trademark

Arzerra Australian Registration Numbers:

AUST R 196945 Arzerra ofatumumab (rmc) 100 mg/5 mL injection concentrate vial

AUST R 218896 Arzerra ofatumumab (rmc) 1000 mg/50 mL injection concentrate vial

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