ARZERRA®

20 mg/mL injection concentrate vial

Ofatumumab (rmc)

Consumer Medicine Information

What is in this leaflet

Please read 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 the lymphocytes (a type of white blood cell). 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 causes the lymphocyte to die.

Your doctor may have prescribed Arzerra for another reason.

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

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). Check with your doctor if you think this may apply to you.
- you have ever had an allergic reaction to any of the ingredients listed toward the end of this leaflet. (See "Ingredients").

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

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 your pharmacist for disposal.

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

Tell your doctor if

Before you are given Arzerra your doctor needs to know:

- if you have had heart problems
- if you have lung disease
- if you have 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.

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.

Infusion reactions

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

If you think you have had an infusion reaction before, tell your doctor before you are given Arzerra.

Progressive multifocal leukoencephalopathy (PML)

Medicines like Arzerra may cause a serious and life threatening brain condition called progressive multifocal leukoencephalopathy (PML).

Tell your doctor immediately if you have memory loss, trouble 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.

Taking other medicines

Tell your doctor 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.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or think you could be, before you are given Arzerra.

There is no information about the safety of Arzerra in pregnant women.

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

Breast-feeding is not recommended during treatment with Arzerra, because it is not known whether it passes into human milk.

Driving and using machines

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

Arzerra contains sodium

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

You need to take this into account if you are on a controlled sodium diet.

How do I use Arzerra?

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

How much to take

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 8 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.

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.

Side effects

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. These reactions normally occur 1 to 2 hours after starting the infusion. They are more likely during the first treatment.

Very common symptoms of an infusion reaction include (these may affect more than 1 in 10 people):

- skin rash
- feeling sick (nausea)
- high temperature

Common symptoms of an infusion reaction include (these may affect up to 1 in 10 people):

- Severe allergic reaction. Signs include:
  - raised and itchy rash (hives)
  - swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
  - collapse
- chills, flushing,

- cough, difficulty in breathing, shortness of breath, chest tightness
- pain in joints, muscles or back
- drop in blood pressure which may make you feel dizzy or lightheaded
- throat pain or irritation
- high blood pressure
- rapid heart beat
- feeling tired
- diarrhoea
- shaking or excessive shivering
- blocked nose
- excessive sweating

Uncommon symptoms of an infusion reaction (this may affect up to 1 in 100 people):

- fluid in the lungs (pulmonary oedema) causing breathlessness
- slow heart beat.

Tell your doctor or a nurse immediately if you get any of these symptoms.

Additional side effects that have been observed with Arzerra:

Very common side effects

These may affect more than 1 in 10 people:

- infections of the lungs or airways (respiratory tract) such as pneumonia
- infections of the ear, nose or throat

Very common side effects that may show up in your blood tests:

- low levels of white blood cells
- low levels of red blood cells (anaemia)

Common side effects

These may affect up to 1 in 10 people:

- a 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 side effects that may show up in your blood tests:

- low levels of platelets in the blood (cells that help blood to clot)

Uncommon side effects

These may affect up to 1 in 100 people:

- increase in potassium, phosphate and uric acid in the blood that can cause kidney problems (tumour lysis syndrome)

The symptoms of this condition include:

- producing less urine than normal
- muscle spasms

If you notice these symptoms, contact your doctor as soon as possible.

Uncommon side effects that may show up in your blood tests:

- problems with blood clotting
- the bone marrow failing to produce enough red or white blood cells

Rare side effects

This may affect up to 1 in 1000 people:

- Infection or reactivation of hepatitis B virus.

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.

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

If you get side effects

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 is Arzerra stored?

Arzerra Concentrate

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

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

Do not freeze.

Keep 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 preparation

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

Discard any unused infusion solution 24 hours after it was prepared. Do not freeze.

Product description

What Arzerra looks like

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

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

Arzerra 1,000 mg is available in a pack containing 1 vial. Each glass vial is closed with a latex-free rubber stopper and aluminium over-seal, and 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

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www.novartis.com.au

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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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For internal use only

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