

Early Access to Medicines Scheme – Treatment protocol – Information for patients

Introduction

Patient enrolment in this EAMS has been closed on 12 June 2017.

As some patients may still be on treatment, the safety information in this Treatment Protocol has been updated (sections 2 and 4) on 19 June 2017.

Contact information regarding queries on the use of this EAMS medicine can be found at the end of this document.

Information for the patient

Atezolizumab 1,200mg concentrate for solution for infusion atezolizumab

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- It is important that you keep your Patient Alert Card with you during treatment and for at least 5 months after completing your treatment with atezolizumab.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What atezolizumab is and what it is used for
2. What you need to know before you are given atezolizumab
3. How atezolizumab is given
4. Possible side effects
5. How to store atezolizumab
6. Contents of the pack and other information

1. What atezolizumab is and what it is used for

What atezolizumab is

Atezolizumab is an anti-cancer medicine that contains the active substance 'atezolizumab'. It is a type of protein that belongs to a group of medicines called 'monoclonal antibodies'. Monoclonal antibodies are a type of protein designed to recognise and attach to a specific target substance in the body.

What atezolizumab is used for

Atezolizumab is being used in the Early Access to Medicines Scheme (EAMS) to treat adults with a type of cancer that affects the bladder and the urinary system, called 'urothelial carcinoma'. It is used in this cancer when it has:

- spread to other parts of the body
- come back after previous treatment.

How atezolizumab works

Atezolizumab works by attaching to a specific protein in your body called programmed death-ligand 1 (PD-L1). This protein makes the immune system in the body work less well. By attaching to the protein, atezolizumab blocks its action and helps your immune system to fight your cancer. Atezolizumab works better if the tumour exhibits a certain level of PD-L1, which is measured in a biopsy.

2. What you need to know before you are given atezolizumab

You must not be given atezolizumab if:

- you are **allergic** to atezolizumab or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor or nurse before you are given atezolizumab.

Warnings and precautions

Talk to your doctor or nurse before you are given atezolizumab if:

- you have an illness such as rheumatoid arthritis, systemic lupus erythematosus or multiple sclerosis - these are called 'auto-immune' illnesses

- you have ever had inflammation of the lungs - this is called 'pneumonitis'
- you are currently suffering from an infection or received treatment for an infection within the last 4 weeks
- you received a live attenuated vaccine within the last 4 weeks.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before you are given atezolizumab.

Atezolizumab may cause some side effects that you must tell your doctor about straight away. They may happen weeks or months after your last dose. Tell your doctor straight away if you notice any of the symptoms below:

- **inflammation of the lung** (pneumonitis): symptoms may include new or worsening cough, shortness of breath, and chest pain
- **inflammation of the liver** (hepatitis): symptoms may include yellowing of skin or eyes, nausea, vomiting, bleeding or bruising, dark urine, and stomach pain
- **inflammation of the intestines** (colitis): symptoms may include diarrhoea (watery, loose or soft stools), blood in stools, and stomach pain
- **inflammation of the thyroid and adrenal glands** (hypo-thyroidism, hyper-thyroidism, or adrenal insufficiency): symptoms may include tiredness, weight loss, weight gain, change in mood, hair loss, constipation, and dizziness
- **type 1 diabetes mellitus**, including acid in the blood produced from diabetes (diabetic ketoacidosis): symptoms may include feeling more hungry or thirsty than usual, need to urinate more often, weight loss, and feeling tired
- **inflammation of the brain** (encephalitis) or inflammation of the membrane around the spinal cord and brain (meningitis): symptoms may include neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, confusion and sleepiness
- **inflammation or problems of the nerves** (neuropathy): symptoms may include muscle weakness and numbness, tingling in hands and feet
- **inflammation of the pancreas** (pancreatitis): symptoms may include abdominal pain, nausea and vomiting
- **inflammation of the heart muscle** (myocarditis); symptoms may include shortness of breath, decreased exercise tolerance, fatigue, chest pain, swelling of your ankles or legs, irregular heartbeat, or fainting
- severe **reactions associated with infusion** (events occurring during or within one day of having the infusion) may include fever, chills, shortness of breath and flushing.

If you notice any of the symptoms above, tell your doctor straight away.

Do not try to treat yourself with other medicines. Your doctor may:

- give you other medicines to prevent complications and reduce symptoms,
- wait longer until your next dose of atezolizumab,
- stop your treatment with atezolizumab.

Tests and checks

Before your treatment, your doctor will check your general health. In order to help your doctor determine whether you may benefit most from atezolizumab, an analysis of your tumour may be performed after a biopsy. You will also have blood tests during your treatment.

Children and adolescents

This medicine should not be given to children or young people below 18 years of age. This is because the effects of atezolizumab in this age group are not known.

Other medicines and atezolizumab

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor if you are taking any medicines that suppress your immune system, such as corticosteroids, since these medicines may interfere with the effect of atezolizumab.

Pregnancy and contraception

- Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant.
- Do not have atezolizumab if you are pregnant unless your doctor has told you to. This is because the effect of atezolizumab in pregnant women is not known - it is possible that it could harm your unborn baby.
- If you could become pregnant, you must use effective contraception;
- while you are being treated with atezolizumab and
- for at least 5 months after the last dose.
- If you become pregnant while you are being treated with atezolizumab tell your doctor immediately.

Breast-feeding

It is not known whether atezolizumab gets into breast milk. A risk to the breast-fed infant cannot be excluded. Ask your doctor if you should stop breast-feeding or if you should stop treatment with atezolizumab.

Driving and using machines

It is not known whether atezolizumab affects your ability to drive or use tools or machines. However, as atezolizumab can cause fatigue, do not drive or use tools or machines if you feel tired and wait until you feel better.

3. How atezolizumab is given

You will be given atezolizumab in a hospital or clinic under the supervision of an experienced doctor.

How much atezolizumab is given

The recommended dose is 1,200 milligrams (mg) every three weeks.

How atezolizumab is given

Atezolizumab is given as a drip into a vein (called an 'intravenous infusion' or 'IV').

Your first infusion will be given over 60 minutes.

- Your doctor will monitor you carefully during the first infusion.
- If you do not have an infusion reaction during the first infusion, the next infusions will be given to you over a period of 30 minutes.

How long treatment lasts

Your doctor will keep giving you atezolizumab until you no longer benefit from it. However, it may be stopped if the side effects become too much of a problem.

If you miss a dose of atezolizumab

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important to keep having the infusions.

If you stop receiving atezolizumab

Do not stop treatment with atezolizumab unless you have discussed this with your doctor. This is because stopping treatment may stop the effect of the medicine.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

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

Tell your doctor straight away if you notice any of the side effects below or if they get worse. They may happen weeks or months after your last dose. Do not try to treat yourself with other medicines.

The following side effects have been reported in clinical trials with atezolizumab:

Very common: may affect more than 1 in 10 people

- loss of appetite
- diarrhoea, nausea, vomiting
- shortness of breath
- feeling very tired with no energy (fatigue)
- lack of energy
- itching of the skin, rash
- fever
- joint pain.

Common: may affect up to 1 in 10 people

- allergic reaction (infusion-related reaction or hypersensitivity)
- chills, flu-like illness, nasal congestion
- difficulty swallowing
- stomach pain
- pain in the muscles and bones
- low blood pressure
- low oxygen levels which may cause shortness of breath
- inflammation of the lungs
- inflammation of the intestines
- underactive thyroid gland (hypo-thyroidism)
- overactive thyroid gland (hyper-thyroidism)
- low platelet count, which may make you more likely to bruise or bleed
- elevated liver enzymes - may be a sign of an inflamed liver (shown in tests)
- low potassium or sodium levels in the blood (shown in tests) (hyponatremia).

Uncommon: may affect up to 1 in 100 people

- inflammation of the liver
- inflammation of the pancreas
- type 1 diabetes
- low levels of adrenal hormones
- numbness or paralysis - these may be signs of 'Guillain Barré' syndrome
- inflammation of the membrane around the spinal cord and brain
- high levels of lipase - may be a sign of an inflamed pancreas (shown in tests).

Rare: may affect up to 1 in 1,000 people

- inflammation of the brain
- inflammation of the heart muscle
- myasthenia gravis - an illness that can cause muscle weakness
- inflammation of the pituitary gland situated at the base of the brain
- high levels of amylase - may be a sign of an inflamed pancreas (shown in tests).

If you notice any of the side effects above or if they get worse, tell your doctor straight away.

5. How to store atezolizumab

Atezolizumab will be stored by the healthcare professionals at the hospital or clinic. The storage details are as follows:

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

- Do not use this medicine after the expiry date which is stated on the carton and the vial label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C to 8 °C). Do not freeze.
- Do not shake.
- Keep the vial in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help to protect the environment.

6. Contents of the pack and other information

What atezolizumab contains

- The active substance is atezolizumab. Each mL contains 60 mg of atezolizumab. Each vial contains 1,200 mg (in 20 mL) of atezolizumab.
- The other ingredients are L-histidine, glacial acetic acid, sucrose, polysorbate 20 and water for injection.

What atezolizumab looks like and contents of the pack

Atezolizumab is a concentrate for solution for infusion. It is a clear, colourless to slightly yellowish liquid. Atezolizumab is available in a pack containing 1 glass vial.

Scientific Opinion Holder

Roche Products Limited
6 Falcon Way
Shire Park
Welwyn Garden City
AL7 1TW
United Kingdom

Manufacturer

Roche Pharma AG
Emil-Barell-Strasse 1
D-79639
Grenzach-Wyhlen
Germany

Date of leaflet preparation: June 2017

Contact information

Contact details for reporting Adverse Events/Special Situations/Pregnancies:

SAE Email Address: welwyn.uk_dsc@roche.com

SAE Facsimile Transmission: +44 1707 367582

SAE TELEPHONE CONTACT: +44 1707 367554

Name: UK Drug Safety Centre

Contact Details for Medical Information

Roche Medical Information on 0800 328 1629 or email medinfo.uk@roche.com