Package leaflet: Information for the patient

Tecentriq 1,875 mg solution for injection
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 the Patient Card with you during treatment.
- 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 Tecentriq is and what it is used for

What Tecentriq is

Tecentriq is an anti-cancer medicine that contains the active substance atezolizumab.
- It belongs to a group of medicines called monoclonal antibodies.
- A monoclonal antibody is a type of protein designed to recognise and attach to a specific target in the body.
- This antibody can help your immune system fight your cancer.

What Tecentriq is used for

Tecentriq is used in adults to treat:
- A kind of bladder cancer, called urothelial carcinoma
- A kind of lung cancer, called non-small cell lung cancer
- A kind of lung cancer, called small cell lung cancer
- A kind of breast cancer, called triple negative breast cancer.
- A kind of liver cancer, called hepatocellular carcinoma

Patients may get Tecentriq when their cancer has spread to other parts of the body or has come back after previous treatment.

Patients may get Tecentriq when their lung cancer has not spread to other parts of the body and treatment will be given after surgery and chemotherapy. Treatment after surgery is called adjuvant therapy.

Tecentriq may be given in combination with other anticancer medicines. It is important that you also read the package leaflets for the other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

How Tecentriq works

Tecentriq works by attaching to a specific protein in your body called programmed death-ligand 1 (PD-L1). This protein suppresses the body's immune (defence) system, thereby protecting cancer cells from being attacked by the immune cells. By attaching to the protein, Tecentriq helps your immune system to fight your cancer.

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

You must not be given Tecentriq

- 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 Tecentriq.

Warnings and precautions

Talk to your doctor or nurse before you are given Tecentriq if you:
- have an auto-immune disease (a condition where the body attacks its own cells)
- have been told that your cancer has spread to your brain
- have any history of inflammation of your lungs (called pneumonitis)
- have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- have a significant cardiovascular (heart) disease or blood disorders or organ damage due to inadequate blood flow
- have had serious side effects because of other antibody therapies that help your immune system to fight cancer
- have been given medicines to stimulate your immune system
- have been given medicines to suppress your immune system
- have been given a live, attenuated vaccine
- have been given medicines to treat infections (antibiotics) in the past two weeks

Tecentriq acts on your immune system. It may cause inflammation in parts of your body. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild.

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

Tecentriq 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, adrenal glands and the pituitary gland (hypothyroidism, hyperthyroidism, adrenal insufficiency or hypophysitis): symptoms may include tiredness, weight loss, weight gain, change in mood, hair loss, constipation, dizziness, headaches, increased thirst, increased urination and changes in vision
- type 1 diabetes, including a serious, sometimes life-threatening problem due to 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, feeling tired or having difficulty thinking clearly, breath that smells sweet or fruity, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, nausea or vomiting, stomach pain, and deep or fast breathing
- 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 weakness in the arm and leg muscles, or face muscles, double vision, difficulties with speech and chewing, numbness, and tingling in hands and feet
- inflammation of the spinal cord (myelitis): symptoms may include pain, abnormal sensations such as numbness, tingling, coldness or burning, weakness in the arms or legs, and bladder and bowel problems
- 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, feeling tired, chest pain, swelling of the ankles or legs, irregular heartbeat, and fainting
- inflammation of the kidneys (nephritis); symptoms may include changes in urine output and colour, pain in pelvis, and swelling of the body and may lead to failure of the kidneys
- inflammation of the muscles (myositis); symptoms may include muscle weakness, fatigue after walking or standing, tripping or falling, and trouble swallowing or breathing
- severe reactions associated with injection (events occurring during the injection or within one day of the injection): may include fever, chills, shortness of breath and flushing
- severe skin reactions (SCARs); which may include rash, itching, skin blistering, peeling or sores, and/or ulcers in the mouth or in lining of the nose, throat or genital area
- inflammation of the heart sac with build-up of fluid in the sac (in some cases) (pericardial disorders): symptoms are similar to those of myocarditis and may include chest pain (usually over the front of the chest, sharp, and worsened by deep breathing and better when you sit up and lean forward in case of inflammation of the heart sac), cough, irregular heartbeat, swelling of the ankles, legs or abdomen, shortness of breath, fatigue, and fainting
- a condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis): symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems

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.
- Delay giving your next dose of Tecentriq.
- Stop your treatment with Tecentriq.

Tests and checks

Before your treatment, your doctor will check your general health. You will also have blood tests during your treatment.

Children and adolescents

This medicine should not be given to children or adolescents below 18 years of age. This is because the safety and efficacy of Tecentriq have not been established in this age group.

Other medicines and Tecentriq

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.

Pregnancy and contraception

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

- You will not be given Tecentriq if you are pregnant unless your doctor considers it necessary. This is because the effect of Tecentriq 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 Tecentriq and
  - for 5 months after the last dose.
- If you become pregnant while you are being treated with Tecentriq tell your doctor.

Breast-feeding

It is not known if Tecentriq gets into breast milk. Ask your doctor if you should stop breast-feeding or if you should stop treatment with Tecentriq.

Driving and using machines

Tecentriq has minor influence on your ability to drive and use machines. If you feel tired, do not drive or use machines until you feel better.

Tecentriq contains Polysorbate

This medicine contains 9 mg of polysorbate 20 in each 15 ml dose, which is equivalent to 0.6 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

Patient Card

Important information from this package leaflet can be found in the Patient Card you have been given by your doctor. It is important that you keep this Patient Card and show it to your partner or caregivers.

Tecentriq SC contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How Tecentriq is given

You will be given Tecentriq by a doctor or nurse experienced in cancer treatment.

Two different types (formulations) of Tecentriq exist:
• one is given as an infusion into a vein (intravenous infusion)
• the other is given as an injection under the skin (subcutaneous injection).

Your doctor may consider switching your subcutaneous Tecentriq treatment to intravenous Tecentriq treatment (and vice versa) if considered appropriate for you.

How much subcutaneous Tecentriq is given

The recommended dose of Tecentriq solution for injection is 1,875 mg every three weeks.

How subcutaneous Tecentriq is given

Tecentriq is given as injection under your skin (subcutaneous injection) by a doctor or nurse.

- Injections will be given in the thigh in approximately 7 minutes
- The injection site will be alternated between the left and right thigh
- Your doctor or nurse will make sure each injection is given in a new place (at least 2.5 cm away from any previous place of injection), and where the skin is not red bruised, tender or hard
- Different places for injection should be used for other medicines

How long treatment lasts

Your doctor will keep giving you Tecentriq 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 Tecentriq

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 injections.

If you stop receiving Tecentriq

Do not stop treatment with Tecentriq 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.

Tecentriq used alone

The following side effects have been reported in clinical trials with Tecentriq used alone:

Very common: may affect more than 1 in 10 people
- fever
- nausea
- vomiting
- feeling very tired with no energy (fatigue)
- lack of energy

- itching of the skin
- diarrhoea
- joint pain
- rash
- loss of appetite
- shortness of breath
- urinary tract infection
- back pain
- cough
- headache

Common: may affect up to 1 in 10 people
- inflammation of the lungs (pneumonitis)
- low oxygen levels, which may cause shortness of breath as a consequence of inflamed lungs (hypoxia)
- stomach pain
- pain in the muscles and bones
- inflammation of the liver
- elevated liver enzymes (shown in tests), which may be a sign of an inflamed liver
- difficulty swallowing
- blood tests showing low levels of potassium (hypokalaemia) or sodium (hyponatremia)
- low blood pressure (hypotension)
- underactive thyroid gland (hypothyroidism)
- allergic reaction (injection-related reaction, hypersensitivity or anaphylaxis)
- flu-like illness
- chills
- inflammation of the intestines
- low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia)
- high blood sugar
- common cold (nasopharyngitis)
- mouth and throat pain, or dry mouth
- dry skin
- abnormal kidney test (possible kidney damage)
- overactive thyroid gland (hyperthyroidism)
- local reaction at injection site
- inflammation of the heart sac with build-up of fluid in the sac (in some cases) (pericardial disorders)
- nerve damage resulting in possible numbness, pain, and/or loss of motor function (peripheral neuropathy)

Uncommon: may affect up to 1 in 100 people
- inflammation of the pancreas
- numbness or paralysis, which may be signs of Guillain-Barré syndrome
- inflammation of the membrane around the spinal cord and brain
- low levels of adrenal hormones
- type 1 diabetes (including diabetic ketoacidosis)
- inflammation of muscles (myositis)
- red, dry, scaly patches of thickened skin (psoriasis)
- inflammation of the kidneys
- itching, skin blistering, peeling or sores, and/or ulcers in the mouth or in lining of nose, throat, or genital area which can be severe (severe skin reactions)
- inflammation of the pituitary gland situated at the base of the brain

- elevated creatine phosphokinase in the blood (shown in test), which may be a sign of muscle or heart inflammation
- changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (lichen disorders)

Rare: may affect up to 1 in 1,000 people
- inflammation of the heart muscle
- myasthenia gravis, an illness that can cause muscle weakness
- inflammation of the eye (uveitis)
- inflammation of the spinal cord (myelitis)
- weakness of facial nerves and muscles (facial paresis)
- haemophagocytic lymphohistiocytosis, a condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms
- coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

Other side effects that have been reported with frequency not known (cannot be estimated from the available data):

- inflammation of the bladder; signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen.
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

Tecentriq used in combination with anticancer medicines

The following side effects have been reported in clinical trials when Tecentriq is given in combination with anticancer medicines:

Very common: may affect more than 1 in 10 people
- low number of red blood cells, which can cause tiredness and shortness of breath
- low white blood cell count with and without fever, which can increase the risk of infection (neutropenia, leukopenia)
- low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia)
- constipation
- nerve damage resulting in possible numbness, pain, and/or loss of motor function (peripheral neuropathy)
- underactive thyroid gland (hypothyroidism)
- loss of appetite
- shortness of breath
- diarrhoea
- nausea
- itching of the skin
- rash
- joint pain
- feeling very tired (fatigue)
- fever
- headache
- cough
- pain in the muscles and bones
- vomiting
- back pain
- lack of energy

- infection of the lung
- common cold (nasopharyngitis)
- hair loss
- high blood pressure (hypertension)
- swelling in arms or legs

Common: may affect up to 1 in 10 people
- blood tests showing low levels of potassium (hypokalaemia) or sodium (hyponatremia)
- inflammation of the mouth or lips
- hoarse voice (dysphonia)
- low levels of magnesium (hypomagnesaemia), which can cause weakness and muscle cramping, numbness and pain in the arms and legs
- protein in urine (proteinuria)
- inflammation of the intestines
- fainting
- elevated liver enzymes (shown in tests), which may be a sign of an inflamed liver
- changes to sense of taste (dysgeusia)
- decreased number of lymphocyte (a type of white blood cells), which is associated with an increased risk of infection
- abnormal kidney test (possible kidney damage)
- overactive thyroid gland (hyperthyroidism)
- dizziness
- injection-related reactions
- severe infection in the blood (sepsis)

Uncommon: may affect up to 1 in 100 people
- red, dry, scaly patches of thickened skin (psoriasis)
- itching, skin blistering, peeling or sores, and/or ulcers in the mouth or in lining of nose, throat, or genital area which can be severe (severe skin reactions)
- inflammation of the heart sac with build-up of fluid in the sac (in some cases) (pericardial disorders)
- inflammation of the pituitary gland situated at the base of the brain

Rare: may affect up to 1 in 1,000 people
- weakness of facial nerves and muscles (facial paresis)
- haemophagocytic lymphohistiocytosis, a condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms
- coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- changes in any area of the skin and/or genital area that are associated with drying out, thinning, itching and pain (lichen disorders)

Other side effects that have been reported with frequency not known (cannot be estimated from the available data):
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or

Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tecentriq

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

- 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 - 8 °C). Do not freeze.
- Keep the vial in the outer carton in order to protect from light. Do not shake.
- Do not use if this medicine is cloudy, discoloured or contains particles.

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 Tecentriq contains

- The active substance is atezolizumab. Each mL contains 125 mg of atezolizumab. One vial of 15 mL solution contains 1,875 mg of atezolizumab.
- The other ingredients are L-histidine, L-methionine, acetic acid, sucrose, polysorbate 20 (see section 2 “Tecentriq contains Polysorbate”), recombinant human hyaluronidase (rHuPH20), and water for injections.

What Tecentriq looks like and contents of the pack

Tecentriq is a solution for injection. It is a clear, colourless to slightly yellowish liquid.

Tecentriq is available in a pack containing 1 glass vial.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in May 2025

The following information is intended for healthcare professionals only:

To prevent medication errors, it is important to check the vial labels to ensure that the appropriate formulation (intravenous or subcutaneous formulation) is being given to the patient as prescribed.

Tecentriq solution for injection should be inspected visually to ensure there is no particulate matter or discolouration prior to administration.

Tecentriq solution for injection is a ready to use solution which should NOT be diluted or mixed with other medicinal products.

Tecentriq solution for injection is for single use only and should be prepared by a healthcare professional.

No incompatibilities have been observed between Tecentriq solution for injection and polypropylene (PP), polycarbonate (PC), stainless steel (SS), polyvinyl chloride (PVC), and polyurethanes (PU).

Preparation of the syringe

From a microbiological point of view, Tecentriq solution for injection should be used immediately once transferred from the vial to the syringe since the medicine does not contain any antimicrobial-preservative or bacteriostatic agents.

- Remove the vial from refrigerated storage and allow the solution to come to room temperature.
- Withdraw the entire contents of Tecentriq solution for injection from the vial with a sterile syringe and transfer needle (18G recommended).
- Remove the transfer needle and attach a subcutaneous infusion set (e.g. winged/butterfly) containing a 23-25G stainless steel needle for injection. Use a subcutaneous infusion set with residual hold-up volume NOT exceeding 0.5 mL for administration.
- Prime the subcutaneous infusion line with the drug product solution to eliminate the air in the infusion line and stop before the fluid reaches the needle.
- Ensure the syringe contains exactly 15 mL of the solution after priming and expelling any excess volume from the syringe.
- Administer immediately to avoid needle clogging. DO NOT store the prepared syringe that has been attached to the already-primed subcutaneous infusion set.

If the dose is not administered immediately, refer to “Storage of the syringe” below.

Storage of syringe

- If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be longer than 24 hours at 2°C to 8°C, unless preparation has taken place under controlled and validated aseptic conditions.
- If the dose is not to be administered immediately, use aseptic technique to withdraw the entire contents of Tecentriq solution for injection from the vial into the syringe to account for the dose volume (15 mL) and priming volume for the subcutaneous infusion set. Replace the transfer needle with a syringe closing cap. DO NOT attach a subcutaneous infusion set for storage.
- The prepared syringe can be stored for up to 30 days at 2 °C to 8 °C and for up to 8 hours at ≤30°C in diffuse daylight from the time of preparation.
- If the syringe is stored in a refrigerator, allow the syringe to reach room temperature prior to administration.

Method of Administration

Tecentriq solution for injection is not intended for intravenous administration and must be given by subcutaneous injection only.

Prior to administration, remove Tecentriq solution for injection from refrigeration and allow the solution to reach room temperature. For instructions on the use and handling of Tecentriq solution for injection prior to administration, refer to Section 6.6 of the summary of product characteristics.

Administer 15 mL of Tecentriq solution for injection subcutaneously in the thigh in approximately 7 minutes. Use of a subcutaneous infusion set (e.g. winged/butterfly) is recommended. DO NOT administer the remaining residual hold-up volume in the tubing to the patient.

The injection site should be alternated between the left and right thigh only. New injections should be given at least 2.5 cm from the old site and never into areas where the skin is red, bruised, tender, or hard. During the treatment course with Tecentriq subcutaneous formulation other medicinal products for subcutaneous administration should preferably be injected at different sites.

Disposal

The release of Tecentriq in the environment should be minimised. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.