**Package leaflet: Information for the patient**

**Tecentriq 1,200 mg concentrate for solution for infusion**
atezolizumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

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 (defense) 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 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

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 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, 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 infusion (events occurring during the infusion or within one day of the infusion): 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

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**

- Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant.
- 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.

## 3. How Tecentriq is given

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

**How much Tecentriq is given**

The recommended dose is either:
- 840 milligrams (mg) every two weeks, or
- 1,200 milligrams (mg) every three weeks, or
- 1,680 milligrams (mg) every four weeks.

**How Tecentriq is given**

Tecentriq is given as a drip into a vein (an intravenous infusion).

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 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 infusions.

**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
- pain in the muscles and bones
- 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
- 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 (infusion-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
- blocked nose (nasal congestion)
- high blood sugar
- common cold
- mouth and throat pain
- dry skin
- abnormal kidney test (possible kidney damage)
- overactive thyroid gland (hyperthyroidism)

**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
- 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)

**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 pituitary gland situated at the base of the brain
- inflammation of the eye (uveitis)

**Other side effects that have been reported** (frequency not known):
- 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.

**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
- 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)
- 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
- infusion-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)

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

## 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.
- The diluted solution should not be kept more than 24 hours at 2 °C to 8 °C or 8 hours at ambient temperature (≤ 25 °C), unless dilution has taken place in controlled and validated aseptic conditions.

- 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 60 mg of atezolizumab. Each 14 mL vial contains 840 mg of atezolizumab. Each 20 mL vial contains 1,200 mg of atezolizumab.
- After dilution, the final concentration of the diluted solution should be between 3.2 and 16.8 mg/mL.
- The other ingredients are L-histidine, glacial acetic acid, sucrose, polysorbate 20 and water for injections.

### What Tecentriq looks like and contents of the pack

Tecentriq is a concentrate for solution for infusion. 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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**United Kingdom**
Roche Products Ltd.
Tel: +44 (0) 1707 366000

**This leaflet was last revised in January 2022.**

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**The following information is intended for healthcare professionals only:**

Instructions for dilution

For the recommended dose of 840 mg: fourteen mL of Tecentriq concentrate should be withdrawn from the vial and diluted into a polyvinyl chloride (PVC), polyolefin (PO), polyethylene (PE), or polypropylene (PP) infusion bag containing sodium chloride 9 mg/mL (0.9%) solution for injection.

For the recommended dose of 1,200mg: twenty mL of Tecentriq concentrate should be withdrawn from the vial and diluted into a polyvinyl chloride (PVC), polyolefin (PO), polyethylene (PE), or polypropylene (PP) infusion bag containing sodium chloride 9 mg/mL (0.9%) solution for injection.

For the recommended dose of 1,680 mg: twenty-eight mL of Tecentriq concentrate should be withdrawn from two vials of Tecentriq 840 mg and diluted into a polyvinyl chloride (PVC), polyolefin (PO), polyethylene (PE), or polypropylene (PP) infusion bag containing sodium chloride 9 mg/mL (0.9%) solution for injection.

After dilution, the final concentration of the diluted solution should be between 3.2 and 16.8 mg/mL. The bag should be gently inverted to mix the solution in order to avoid foaming. Once the infusion is prepared it should be administered immediately.

Parenteral medicinal products should be inspected visually for particulates and discolouration prior to administration. If particulates or discoloration are observed, the solution should not be used.

No incompatibilities have been observed between Tecentriq and intravenous bags with product-contacting surfaces of PVC, PO, PE, or PP. In addition, no incompatibilities have been observed with in-line filter membranes composed of polyethersulfone or polysulfone, and infusion sets and other infusion aids composed of PVC, PE, polybutadiene, or polyetherurethane. The use of in-line filter membranes is optional.

Diluted solution

Chemical and physical in-use stability has been demonstrated for up to 24 hours at ≤ 30 °C and for up to 30 days at 2 °C to 8 °C from the time of preparation.

From a microbiological point of view, the prepared solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 °C to 8 °C or 8 hours at ambient temperature (≤ 25 °C), unless dilution has taken place in controlled and validated aseptic conditions.

Method of administration

Tecentriq is for intravenous use. The infusions must not be administered as an intravenous push or bolus.

The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is well tolerated all subsequent infusions may be administered over 30 minutes.

Do not co-administer other medicinal products through the same infusion line.

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.