

Tecentriq®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Tecentriq?

Tecentriq contains the active ingredient atezolizumab. Tecentriq is used to treat different types of cancers.

For more information, see Section [1. Why am I using Tecentriq?](#) in the full CMI.

2. What should I know before I use Tecentriq?

Do not use if you have ever had an allergic reaction to Tecentriq or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Tecentriq?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tecentriq and affect how it works.

For more information see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Tecentriq?

Tecentriq is given by a slow drip into a vein (intravenous (IV) infusion) by a doctor or nurse once every two, three or four weeks. The first infusion will be over 60 minutes. If the first infusion is well tolerated, your infusion time may be shortened to 30 minutes. More instructions can be found in Section [4. How do I use Tecentriq?](#) in the full CMI.

5. What should I know while using Tecentriq?

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| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Tecentriq.• Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. |
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|----------------------------------|---|
| Driving or using machines | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Tecentriq affects you. |
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For more information, see Section [5. What should I know while using Tecentriq?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Tecentriq can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

When you are using Tecentriq, you can have some serious side effects. Serious side effects associated with Tecentriq may include lung problems, liver problems, intestinal problems, heart problems, muscle problems, kidney problems, problems in hormone glands (for example thyroid, pituitary, adrenal problems or diabetes), the nervous system, the skin, the immune system, abnormal production or breakdown of red blood cells, eye problems, and problems with other organs. The most common side effects when Tecentriq is used on its own include diarrhoea, nausea, vomiting, urinary tract infection, decreased appetite, feeling tired or weak, fever, cough, shortness of breath, rash, itchy skin and headache. The most common side effects when Tecentriq was given in combination with other anti-cancer medicines include feeling tired or weak, constipation, swelling of legs or arms, lung infections,

hair loss, high blood pressure, common cold, and pain, swelling or stiffness of joints,.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Tecentriq (Tee-sen-trik)

Active ingredient(s): *atezolizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tecentriq. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tecentriq.**

Where to find information in this leaflet:

- [1. Why am I using Tecentriq?](#)
- [2. What should I know before I use Tecentriq?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Tecentriq?](#)
- [5. What should I know while using Tecentriq?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Tecentriq?

Tecentriq contains the active ingredient atezolizumab. Tecentriq works by attaching to a specific protein in your body called 'PD-L1'. This protein makes the immune system in the body work less well. By attaching to the protein, Tecentriq works by helping your immune system fight your cancer.

Tecentriq may be given in combination with other medicines. It is important you read the Consumer Medicine Information for those medicines. Please ask your doctor if you have any questions about Tecentriq or any other medicines used with Tecentriq.

Tecentriq is used to treat:

- non-small cell lung cancer, when the lung cancer has not spread to other parts of the body. Treatment will be given after surgery takes place and after chemotherapy has been given.
- non-small cell lung cancer, when the lung cancer has spread to other parts of the body. Tecentriq is used together with other medicines (bevacizumab, paclitaxel and carboplatin; or nab-paclitaxel and carboplatin). Tecentriq can also be used as a single treatment (monotherapy) if the cancer has come back after previous treatment.
- a type of cancer that affects the bladder and the urinary system, called “urothelial carcinoma”.
- a type of cancer that affects the lungs, called small cell lung cancer (SCLC). Tecentriq is used together with the chemotherapy medicines etoposide and carboplatin.
- a type of cancer that affects the liver called hepatocellular carcinoma. Tecentriq is used together with a medicine called bevacizumab when the liver cancer is unable to be removed by surgery or has spread to other parts of the body

2. What should I know before I use Tecentriq?

Warnings

Do not use Tecentriq if:

- you are allergic to atezolizumab, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you:

- have any immune system problems. You may have an increased risk of experiencing an immune-mediated adverse reaction
- have inflammation of the lungs (called ‘pneumonitis’)
- have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome
- have liver problems, such as hepatitis
- have thyroid problems
- have been given a live, attenuated vaccine recently
- have been told your cancer has spread to your brain
- take any medicines for any other condition
- have any allergies to any other medicines, foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant. Tecentriq can harm your unborn baby.

If you are a woman who is able to become pregnant, you should use an effective method of birth control during your treatment with Tecentriq and for at least 5 months after your last dose of Tecentriq. Talk to your healthcare provider about birth control methods that you can use during this time.

Tell your doctor right away if you become pregnant during treatment with Tecentriq.

Tell your doctor if you are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with Tecentriq.

It is not known if Tecentriq passes into your breastmilk. A risk to the breastfed infant cannot be excluded.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Tell your doctor or pharmacist if you are taking other medicines that make your immune system weak, such as immunosuppressants and/or steroids

Some medicines may interfere with Tecentriq and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tecentriq.

4. How do I use Tecentriq?

How to use Tecentriq

Tecentriq is prepared by a prepared by a healthcare professional and given by a drip into a vein (called an "intravenous infusion" or "IV").

Your first infusion of Tecentriq will be given over 60 minutes. Your doctor will monitor you carefully during the first infusion. If you do not have an infusion reaction, the next infusion may be given over 30 minutes.

When to use Tecentriq

- Tecentriq is given every two weeks, every three weeks or every four weeks.
- Your doctor will decide how long you should receive Tecentriq, this will depend on your response to the medicine and the state of your disease. If you are receiving Tecentriq for lung cancer after surgery, you may receive Tecentriq for up to 1 year.

If you forget to use Tecentriq

As Tecentriq is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Tecentriq, make another appointment as soon as possible.

If you use too much Tecentriq

As Tecentriq is given under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given Tecentriq, tell your doctor immediately.

5. What should I know while using Tecentriq?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving Tecentriq.

Tell any other doctors, dentists, and pharmacists who treat you that you are receiving this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are a woman who is able to become pregnant, you must use effective contraception while you are being treated with Tecentriq and for at least 5 months after the last dose.

If you become pregnant while you are being treated with Tecentriq tell your doctor.

Ask your doctor if you should stop breastfeeding or if you should stop treatment with Tecentriq.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Tecentriq affects you. It is not known whether Tecentriq may impair your ability to drive or operate machinery.

6. Are there any side effects?

Like all medicines, Tecentriq can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tecentriq may cause side effects that appear weeks or months after your last dose. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than

one side effect at the same time. Some side effects can only be found when your doctor does blood tests from time to time to check your progress.

If you have any of the following symptoms, call or see your doctor right away.

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Signs and symptoms of lung problems:</p> <ul style="list-style-type: none">• new or worsening cough• chest pain <p>Signs and symptoms of liver problems:</p> <ul style="list-style-type: none">• yellowing of skin and/or eyes• nausea and/or vomiting• bleeding or bruising• dark urine• stomach pain <p>Signs and symptoms of intestinal problems:</p> <ul style="list-style-type: none">• diarrhoea (watery, loose or soft stools)• blood in stools | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • stomach pain <p>Signs and symptoms of thyroid problems:</p> <ul style="list-style-type: none"> • tiredness • weight loss or weight gain • changes in mood or behaviour • visual disturbances • increased sensitivity to cold or heat • slow or rapid heart rate • hair loss • constipation • headache and/or dizziness <p>Signs and symptoms of blood sugar problems (type 1 diabetes mellitus) and acid in the blood caused by diabetes (diabetic ketoacidosis):</p> <ul style="list-style-type: none"> • feeling more hungry or thirsty than usual • need to urinate more often | |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • weight loss • feeling tired <p>Signs and symptom of problems with the brain and the membrane around the spinal cord and brain:</p> <ul style="list-style-type: none"> • neck stiffness • headache • fever • chills • vomiting • eye sensitivity to light • confusion and sleepiness • muscle weakness in the legs and arms • problems with mobility, the bladder and bowel <p>Signs and symptoms of problems with the nerves:</p> <ul style="list-style-type: none"> • muscle weakness, numbness or tingling in hands and feet | |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • difficulty with facial movements • pins and needles sensation in your fingers and toes • inability to walk or climb stairs • paralysis of the facial muscles <p>Signs and symptoms of problems with the pancreas:</p> <ul style="list-style-type: none"> • abdominal pain • nausea and/or vomiting <p>Signs and symptoms of problems with the heart:</p> <ul style="list-style-type: none"> • shortness of breath • difficulty breathing and speaking • feeling tired • irregular heart beat and/or pounding/ racing heart beat (palpitations) • chest pain • fainting and/or light-headedness | |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • swelling of legs or abdomen • pale and/or clammy skin <p>Signs and symptoms of problems with the muscles:</p> <ul style="list-style-type: none"> • muscle pain or stiffness • skin rash <p>Signs and symptoms of problems with the kidneys:</p> <ul style="list-style-type: none"> • change in urine output and/or colour • pain in pelvis • swelling of the body (oedema) <p>Signs and symptoms of infusion reactions (including anaphylaxis):</p> <ul style="list-style-type: none"> • fever • chills • flushing • wheezing or difficulty breathing | |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin <p>Signs and symptoms of severe skin reactions:</p> <ul style="list-style-type: none"> • rash • itching • skin blistering, peeling or sores • ulcers in the mouth or in lining of the nose, throat or genital area <p>Signs and symptoms of excessive activation of the immune system:</p> <ul style="list-style-type: none"> • fever • swollen lymph nodes • skin rash • yellow colour of the skin and eyes (jaundice) • lung (coughing, difficulty breathing), stomach (vomiting, diarrhoea) and nervous system | |

| Serious side effects | What to do |
|--|------------|
| <p>(headache, changes in vision, weakness) symptoms</p> <p>Abnormal production or breakdown of red blood cells (aplastic or haemolytic anaemia):</p> <ul style="list-style-type: none"> • tiredness, weakness or dizziness, yellow skin (jaundice), shortness of breath <p>Signs and symptoms of uveitis (inflammation of the eye):</p> <ul style="list-style-type: none"> • eye pain, redness, light sensitivity, dark floating spots in vision and blurred vision <p>Signs and symptoms of systemic inflammatory disorder (sarcoidosis):</p> <ul style="list-style-type: none"> • shortness of breath • cough • chest discomfort and/or pain • tender, painful, reddish bumps or patches on the skin | |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> • swollen and painful joints • swollen lymph nodes • eye pain • blurry vision and/or light sensitivity | |

The following side effects have also been reported, in addition to the serious side effects above:

| Side effects | What to do |
|---|---|
| <p>The following side effects were reported when Tecentriq was given alone (monotherapy)</p> <p>Signs and symptoms of lung problems</p> <ul style="list-style-type: none"> • feeling tired with no energy (fatigue) • cough <p>Signs and symptoms of problems with your heart</p> <ul style="list-style-type: none"> • dizziness or light-headedness | <p>Speak to your doctor straight away if you have any of these side effects.</p> |

| Side effects | What to do |
|---|------------|
| <p>Signs and symptoms of problems with your kidneys</p> <ul style="list-style-type: none"> • strong and frequent urge to urinate • cloudy, bloody, or strong-smelling urine • pain or a burning sensation when urinating <p>Signs and symptom of problems with your blood pressure</p> <ul style="list-style-type: none"> • dizziness or light headedness • fainting • lack of concentration <p>Signs and symptoms of low oxygen levels in your blood (hypoxia):</p> <ul style="list-style-type: none"> • changes of the colour of your skin • sweating <p>Signs and symptoms of arthritis:</p> | |

| Side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • pain, swelling, stiffness and/or warmth in the joints <p>Signs and symptoms of problems in other organs:</p> <ul style="list-style-type: none"> • bleeding, bruising or blood in the urine or stool • red, itchy scaly patches of skin, including dry and cracked skin • dry skin • sore throat • difficulty swallowing • common cold • flu-like symptoms • nasal congestion • back, muscle, bone, tendon, joint or nerve pain • generalised weakness, tiredness and droopy eyelids • loss of appetite • low white blood cell count, which can | |

| Side effects | What to do |
|---|------------|
| <p>increase the risk of infection</p> <ul style="list-style-type: none"> • • The following side effects were reported in clinical trials when Tecentriq was given in combination with other medicines (in addition to those above). <p>Signs and symptoms of low iron in your blood (anaemia)</p> <ul style="list-style-type: none"> • tiredness • headaches • being short of breath when exercising • dizziness • looking pale <p>Signs and symptoms of problems with your lungs</p> <ul style="list-style-type: none"> • bronchitis • infections such as pneumonia <p>Signs and symptom of problems with your kidneys (proteinuria)</p> | |

| Side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • foamy or bubbly urine • swelling in the face, feet or ankles • muscle cramps at night <p>Signs and symptom of problems with your blood pressure</p> <ul style="list-style-type: none"> • severe headaches • nose bleeds • irregular heartbeat <p>Signs and symptoms of problems in other organs:</p> <ul style="list-style-type: none"> • a change in the way things taste • inflamed and sore mouth, mouth ulcers and/or cold sores • dry mouth • constipation • changes in your voice or hoarseness • hair loss • swelling to the arms and legs (peripheral oedema) | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Tecentriq contains

| | |
|---|----------------------------------|
| Active ingredient (main ingredient) | atezolizumab |
| Other ingredients (inactive ingredients) | glacial acetic acid histidine |

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| | sucrose polysorbate 20 water for injections |
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Do not take this medicine if you are allergic to any of these ingredients.

What Tecentriq looks like

Tecentriq is a colourless to slightly yellow solution. Tecentriq is supplied as a single use glass vial and is available in two presentations:

- 840 mg of atezolizumab in 14 mL solution (AUST R 310681) and
- 1200 mg of atezolizumab in 20 mL solution (AUST R 277120)

Who distributes Tecentriq

Tecentriq is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30 – 34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950 or via
www.medinfo.roche.com/australia

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