

Tecentriq SC[®]

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. This CMI is for the subcutaneous dosage form of Tecentriq. For information about the intravenous dosage form of Tecentriq, please refer to the intravenous Tecentriq CMI.

1. Why am I using Tecentriq SC?

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

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

2. What should I know before I use Tecentriq SC?

Do not use if you have ever had an allergic reaction to atezolizumab 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 SC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tecentriq SC 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 SC?

Tecentriq solution for subcutaneous (SC) injection is given as an injection under your skin by a doctor or nurse every three weeks. The injection will be given in the thigh over approximately 7 minutes. More instructions can be found in Section [4. How do I use Tecentriq SC?](#) in the full CMI.

5. What should I know while using Tecentriq SC?

| | |
|-----------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Tecentriq SC. |
|-----------------------------|---|

| | |
|----------------------------------|---|
| | <ul style="list-style-type: none"> • Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. |
| Driving or using machines | <ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how Tecentriq SC affects you. |

For more information, see Section [5. What should I know while using Tecentriq SC?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Tecentriq SC 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 SC, you can have some serious side effects. Serious side effects associated with Tecentriq SC 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 atezolizumab 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 atezolizumab 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 SC (Tee-sen-trik S-C)

Active ingredient(s): *atezolizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tecentriq SC. **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 SC.**

Where to find information in this leaflet:

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

1. Why am I using Tecentriq SC?

Tecentriq SC contains the active ingredient atezolizumab. Tecentriq SC 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 SC works by helping your immune system fight your cancer.

Tecentriq SC 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 SC or any other medicines used with Tecentriq SC.

Tecentriq SC 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 SC is used together with other medicines (bevacizumab, paclitaxel and carboplatin; or nab-paclitaxel and carboplatin). Tecentriq SC 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 SC is used together with the chemotherapy medicines etoposide and carboplatin.
- a type of cancer that affects the liver called hepatocellular carcinoma. Tecentriq SC 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 SC?

Warnings

Do not use Tecentriq SC 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 SC 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 SC and for at least 5 months after your last dose of Tecentriq SC. 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 SC.

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

It is not known if Tecentriq SC 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 SC 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 SC.

4. How do I use Tecentriq SC?

How to use Tecentriq solution for subcutaneous (SC) injection

Tecentriq SC is given as an injection under your skin (subcutaneous injection) by a doctor or a nurse. Injections will be given in the thigh over approximately 7 minutes. Your doctor or nurse will make sure each injection is given in a new place (at least 2.5 cm away from any previous injection), and where the skin is not red, bruised, tender or hard. Different places for injection should be used for other medicines.

When to use Tecentriq SC

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

If you forget to use Tecentriq SC

As Tecentriq SC 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 SC, make another appointment as soon as possible.

If you use too much Tecentriq SC

As Tecentriq SC 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 SC, tell your doctor immediately.

5. What should I know while using Tecentriq SC?

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 SC.

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 SC and for at least 5 months after the last dose.

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

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

Driving or using machines

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

6. Are there any side effects?

Like all medicines, Tecentriq SC 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 SC 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• stomach pain | <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 |
|---|------------|
| <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 • weight loss • feeling tired | |

| Serious side effects | What to do |
|---|------------|
| <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 • difficulty with facial movements • pins and needles sensation in your fingers and toes | |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • 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 • swelling of legs or abdomen • pale and/or clammy skin <p>Signs and symptoms of problems with the muscles:</p> | |

| Serious side effects | What to do |
|--|------------|
| <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 whole body (systemic) reactions (including anaphylaxis):</p> <ul style="list-style-type: none"> • fever • chills • flushing • wheezing or difficulty breathing • 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 | |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • 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 (headache, changes in vision, weakness) symptoms <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 | |

| Serious side effects | What to do |
|---|------------|
| <p>(jaundice), shortness of breath</p> <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 • 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 atezolizumab 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>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 | <p>Speak to your doctor straight away if you have any of these side effects.</p> |

| Side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> • 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> <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 | |

| Side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • red, itchy scaly patches of skin, including dry and cracked skin • dry skin • local reaction at injection site • 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 increase the risk of infection <p>The following side effects were reported in clinical trials when atezolizumab was given in combination with other medicines (in addition to those above).</p> | |

| Side effects | What to do |
|---|------------|
| <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> <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 | |

| Side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> • 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 SC contains

| | |
|---|--|
| Active ingredient (main ingredient) | atezolizumab |
| Other ingredients (inactive ingredients) | vorhyaluronidase alfa histidine acetic acid methionine sucrose polysorbate 20 water for injections |

Do not take this medicine if you are allergic to any of these ingredients.

What Tecentriq SC looks like

Tecentriq SC is a colourless to slightly yellow solution. Tecentriq SC is supplied as a single use glass vial and is available in one presentation:

- 1875 mg of atezolizumab in 15 mL solution (AUST R 400555)

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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