

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Tecentriq®

Atezolizumab

Consumer Medicine Information

This medicine has provisional approval in Australia for the treatment of locally advanced or metastatic triple-negative breast cancer. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

What is in this leaflet

This leaflet answers some common questions about Tecentriq. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tecentriq against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tecentriq is used for

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 helps your immune system to fight your cancer.

Tecentriq is used to treat the following cancers once they are advanced and/or spread to other parts of the body (metastatic):

- a type of cancer that affects the lungs, called non-small cell lung cancer. 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 breasts called triple-negative breast cancer. It is used if you have not received prior chemotherapy for this type of cancer. Tecentriq will be given to you together with nab-paclitaxel.
- 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.

Ask your doctor if you have any questions why Tecentriq has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

If you are being treated with Tecentriq together 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.

Before you are given Tecentriq

If you are not sure if you should start receiving Tecentriq, talk to your doctor.

When you must not take it

Do not take Tecentriq if you have an allergy to:

- atezolizumab or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Before you start to take it

Tell your doctor:

- if you have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- if you have inflammation of the lungs (called 'pneumonitis')
- if you have been told your cancer has spread to your brain
- if you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome
- if you have liver problems, such as hepatitis
- if you have thyroid problems
- if you have been given a live, attenuated vaccine

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.

It is not known if Tecentriq passes into your breastmilk.

Do not breastfeed during treatment with Tecentriq.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you start receiving Tecentriq.

Taking other medicines

Tell your doctor or pharmacist if you:

- are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop
- are taking other medicines that make your immune system weak, such as immunosuppressants and/or steroids

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving Tecentriq.

How Tecentriq is given

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

Tecentriq must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse.

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

Depending on the type of cancer Tecentriq is being used to treat, and the stage of treatment, it may be given every two weeks, every three weeks or every four weeks.

If you are given other medicines with Tecentriq, your doctor will determine how much of these to give to you.

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 during the first infusion, the next infusions will be given to you over a period of 30 minutes.

The number of infusions you will be given depends on how you respond to treatment.

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

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 take too much (overdose)

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.

While you are using Tecentriq

Things you must 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.

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

Do not have Tecentriq if you are pregnant unless your doctor has told you to.

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 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.

It is not known whether Tecentriq gets into breast milk. A risk to the breastfed infant cannot be excluded.

Things to be careful of

Be careful driving or operating machinery until you know how Tecentriq affects you.

It is not known whether Tecentriq may impair your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tecentriq.

Tecentriq may cause side effects that appear weeks or months after your last dose.

All medicines can have 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 be given with other medicines to treat cancer so it may be difficult for your doctor to tell whether the side effects are due to Tecentriq or due to other medicines.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor straight away if you notice any of the side effects below or if they get worse. Do not try to treat yourself with other medicines.

The following side effects were reported in clinical trials when Tecentriq was given alone (monotherapy).

- loss of appetite
- diarrhoea
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- feeling tired with no energy (fatigue)
- itching of the skin
- nausea
- fever
- chills
- rash
- vomiting
- difficulty swallowing
- flu-like symptoms
- nasal congestion
- shortness of breath or difficulty breathing
- stomach pain
- back, muscle, bone, tendon, joint or nerve pain
- sore throat
- headache
- symptoms of low blood pressure including dizziness or light headedness, nausea, fainting, lack of concentration
- common cold
- symptoms of urinary tract infection including strong and frequent urge to urinate, cloudy, bloody, or strong-smelling urine,

pain or a burning sensation when urinating

- cough
- dizziness, light-headedness, difficulty breathing and speaking, chest pain
- generalised weakness, tiredness and droopy eyelids
- bleeding, bruising or blood in the urine or stool
- symptoms of hypoxia (low oxygen levels in your blood), including changes of the colour of your skin, fast or slow heart rate, sweating, wheezing, confusion
- dry skin
- red, itchy scaly patches of skin, including dry and cracked skin
- pain and redness of the eye, including light sensitivity, dark floating spots in vision and blurred vision
- symptoms of a condition called Guillain-Barre syndrome, which includes difficulty with facial movements, pins and needles sensation in your fingers and toes, inability to walk or climb stairs

The following side effects were reported in clinical trials when Tecentriq was given in combination with other medicines (in addition to those above).

- low white blood cell count which can increase the risk of infection
- inflamed and sore mouth, mouth ulcers and/or cold sores
- constipation
- symptoms of anaemia including tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- a change in the way things taste
- lung conditions such as bronchitis and infections such as pneumonia
- fainting
- changes in your voice or hoarseness
- hair loss
- swelling to the arms and legs (peripheral oedema)

- protein in your urine (proteinuria): symptoms may include foamy or bubbly urine, swelling in the face, feet or ankles, lack of appetite, muscles cramps at night
- high blood pressure: symptoms include severe headaches, nose bleeds, irregular heartbeat, chest pains

If any of the following happen, tell your doctor immediately:

- 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, pituitary or adrenal glands (hypothyroidism, hyperthyroidism, hypophysitis or adrenal insufficiency): symptoms may include tiredness, weight loss, 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 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 and the membrane around the spinal cord and brain (meningoencephalitis): 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, numbness or 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, feeling tired, irregular heart beat or chest pain
- inflammation of muscles (myositis): symptoms may include muscle pain or stiffness, or skin rash
- inflammation of the kidneys (nephritis): symptoms may include change in urine output and/or colour, pain in pelvis, swelling of the body (oedema)
- severe reactions associated with infusion (including anaphylaxis and other hypersensitivity reactions): symptoms may include 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does blood tests from time to time to check your progress (for example, elevated liver enzymes, low potassium, magnesium or sodium levels, low platelet count, low white blood cell count, high blood sugar, increased alkaline phosphatase levels, increased creatinine levels).

Product description

Storage

Tecentriq will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

Availability

Tecentriq is supplied as a single-dose glass vial in two presentations:

- 840 mg of atezolizumab in 14 mL solution and
- 1200 mg of atezolizumab in 20 mL solution

Tecentriq is diluted before infusion into a vein.

What Tecentriq looks like

Tecentriq is a colourless to slightly yellow solution.

Ingredients

Each vial of Tecentriq contains 840 mg or 1200 mg of the active ingredient atezolizumab.

It also contains:

- glacial acetic acid
- histidine
- sucrose
- polysorbate 20
- water for injections.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Manufacturer

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

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Numbers

- 840 mg vial: AUST R 310681
- 1200 mg vial AUST R 277120

This leaflet was prepared on 30 October 2020