TEVIMBRA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before being given this medicine.

1. Why am I being given TEVIMBRA?

TEVIMBRA contains the active ingredient tislelizumab. TEVIMBRA is used to treat different kinds of cancer.

For more information, see Section 1. Why am I being given TEVIMBRA? in the full CMI.

2. What should I know before I am given TEVIMBRA?

You should be not given TEVIMBRA if you have ever had an allergic reaction to tislelizumab 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 am given TEVIMBRA? in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is TEVIMBRA given?

- TEVIMBRA will be given to you by an experienced doctor and/or nurse.
- TEVIMBRA will be given to you by intravenous (IV) infusion directly into your vein.
- Your doctor will determine how many treatments you need.

More instructions can be found in Section 4. How is TEVIMBRA given? in the full CMI.

5. What should I know while being given TEVIMBRA?

Things you should do	• Remind any doctor, dentist or pharmacist that you are being given TEVIMBRA. • If you miss a dose of TEVIMBRA, call your doctor right away to reschedule your appointment.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how TEVIMBRA affects you.

For more information, see Section 5. What should I know while being given TEVIMBRA? in the full CMI.

6. Are there any side effects?

Like all medicines, TEVIMBRA can cause side effects, however not everybody will experience them. Your doctor will discuss potential side effects with you and explain the risks and benefits of your treatment.

When you are given TEVIMBRA you can have some serious side effects.

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.

▼ 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.

TEVIMBRA®

Active ingredient: *tislelizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TEVIMBRA. **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 TEVIMBRA.**

Where to find information in this leaflet:

1. Why am I being given TEVIMBRA?
2. What should I know before I am given TEVIMBRA?
3. What if I am taking other medicines?
4. How is TEVIMBRA given?
5. What should I know while being given TEVIMBRA?
6. Are there any side effects?
7. Product details

1. Why am I being given TEVIMBRA?

TEVIMBRA contains the active ingredient tislelizumab. TEVIMBRA is an immune checkpoint inhibitor that works by helping your immune system fight your cancer.

TEVIMBRA is used to treat:

- a kind of cancer called oesophageal carcinoma in adults.
- a kind of lung cancer called non-small cell lung cancer in adults.
- a kind of cancer called gastric/gastro-oesophageal junction adenocarcinoma (stomach cancer) in adults.
- a kind of head and neck cancer called nasopharyngeal cancer in adults.

2. What should I know before I am given TEVIMBRA?

Warnings

You should not be given TEVIMBRA if:

- you are allergic to tislelizumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can receive this medicine.

Check with your doctor if you have or have had:

- an autoimmune disease (a condition where the body attacks its own cells)
- inflammation of the liver (hepatitis) or other liver problems
- inflammation of the kidney (nephritis)
- pneumonia or inflammation of your lungs (pneumonitis)
- inflammation of the large bowel (colitis)
- serious rash
- problems with hormone producing glands (including the adrenal, pituitary, and thyroid glands)
- diabetes mellitus
- a solid organ transplant
- infusion-related reaction

Any of these conditions may affect the likelihood of you experiencing an adverse reaction after being given TEVIMBRA.

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

Check with your doctor if you are pregnant or intend to become pregnant.

TEVIMBRA may cause harm to your unborn baby.

You must use effective contraception methods for at least 4 months following your last TEVIMBRA treatment if you are a woman who could become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed whilst being treated with TEVIMBRA.

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.

It is especially important to tell your doctor or pharmacist if you take other medicines that make your immune system weak, such as some steroids.

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

4. How is TEVIMBRA given?

How much and when to take TEVIMBRA

- Your doctor will give you TEVIMBRA by intravenous (IV) infusion directly into your vein.
- Infusions may be administered every 2, 3 or 4 weeks, and may take between 30 and 90 minutes, depending

on the strength of the dose you are receiving and how many doses you have previously received.

- Your doctor will decide how many treatments you need.
- Some types of cancer are treated with TEVIMBRA in combination with other prescription anti-cancer medicines.
- Please refer to the Consumer Medicine Information of any other prescription anti-cancer medicines you are receiving in order to understand the use of these other medicines. If you have questions about these medicines, please ask your doctor.

If you miss an appointment to be given TEVIMBRA

- Call your doctor to reschedule as soon as possible.
- It is important that you do not miss a dose of TEVIMBRA.

5. What should I know while being given TEVIMBRA?

Things you should do

Tell any other doctors, dentists or pharmacists you visit that you are being given TEVIMBRA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given TEVIMBRA.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TEVIMBRA affects you.

Fatigue has been reported following administration of TEVIMBRA.

Looking after your medicine

TEVIMBRA is usually stored in the pharmacy or on the ward. It is unlikely that you will be asked to store TEVIMBRA yourself.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When you are given TEVIMBRA, you can have some serious side effects.

These side effects can sometimes become life-threatening and can lead to death. They may happen at any time during treatment, or after your treatment has ended. It is possible that you may experience more than one side effect at the same time.

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

Serious side effects

Serious side effects	What to do
Signs and symptoms of hormone problems • Fatigue, swelling at base of the neck, pain in front of the throat - possible symptoms of thyroid inflammation (thyroiditis) • Frequent headaches, vision changes (either low vision or double vision), fatigue and/or weakness, confusion, decreased blood pressure, dizziness - possible symptoms of inflammation of the pituitary gland (hypophysitis) **Signs and symptoms of metabolism or nutrition problems** • Increased blood sugar levels, thirst, dry mouth, frequent urination, tiredness, increased appetite with	**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.**

Serious side effects	What to do
weight loss, confusion, nausea, vomiting, fruity-smelling breath, difficulty breathing and dry or flushed skin - potential symptoms of high blood sugar (hyperglycaemia) • High blood sugar, feeling more hungry or thirsty than normal, passing urine more often than normal - possible symptoms of diabetes mellitus **Signs and symptoms of eye problems** • Eye redness, eye pain and swelling - possible symptoms of inflammation of the uvea, the layer beneath the white of the eyeball (uveitis) **Signs and symptoms of lung problems** • Shortness of breath, cough or chest pain - potential symptoms	

Serious side effects	What to do
of lung inflammation (pneumonitis) • Difficulty breathing **Signs and symptoms of nerve problems** • Serious inflammation of the nerves, which may cause difficulty breathing, sensation of prickling or pins and needles in the fingers, toes, ankles or wrists, weakness in the legs that spreads to the upper body, unsteady walking or inability to walk or climb stairs, difficulty with facial movements including speaking, chewing or swallowing, double vision or inability to move eyes, difficulty with bladder control or bowel function, rapid heart rate and paralysis - Guillain-Barré syndrome	

Serious side effects	What to do
Signs and symptoms of heart problems • Chest pain, rapid or abnormal heartbeat, shortness of breath at rest or during activity, fluid build-up with swelling of the legs, ankles and feet, tiredness - possible symptoms of heart muscle inflammation (myocarditis) • Chest pain, fever, cough, palpitations - possible symptoms of inflammation of the membrane around the heart (pericarditis) **Signs and symptoms of stomach and abdomen problems** • Severe upper stomach pain, nausea, vomiting, fever, tender abdomen - possible symptoms of inflammation of the pancreas (pancreatitis)	

Serious side effects	What to do
• Diarrhoea or more bowel movements than normal, black tarry, sticky stools, blood or mucus in stools, severe pain or tenderness in the stomach - possible symptoms of inflammation of the intestines (colitis, coeliac disease, pancreatic exocrine insufficiency) • Inflammation of the stomach lining - which may include severe stomach pain or tenderness, nausea or vomiting (gastritis) **Signs and symptoms of liver problems** • Nausea, vomiting, loss of appetite, pain on the right side of the stomach, yellowing of the skin or the whites of the eyes, drowsiness, dark-coloured urine, bleeding or bruising more easily than normal - possible symptoms	

Serious side effects	What to do
of liver inflammation (hepatitis) **Signs and symptoms of infusion related problems** • Chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness or fever which may occur during infusion or up to 24 hours after infusion - possible symptoms of infusion-related reactions **Signs and symptoms of skin problems** • Itching or peeling skin, skin sores - possible symptoms of severe skin reactions or erythema multiforme • Serious rash and reddening of the skin on upper body and quickly spreading to other parts, blistering of the lips, eyes or mouth, skin peeling, sometimes	

Serious side effects	What to do
with flu-like symptoms such as, fever, sore throat, cough, and joint pain (all of these are possible signs of one of the following skin conditions: Stevens-Johnson syndrome (SJS) or Toxic epidermal necrolysis (TEN)) **Signs and symptoms of brain and nervous system problems** • Confusion, fever, memory problems or seizures - possible symptoms of inflammation of the brain (encephalitis) **Signs and symptoms of muscle or joint problems** • Muscle pain, stiffness, weakness, chest pain, or severe tiredness - possible symptoms of muscle inflammation (myositis) • Joint pain, stiffness, swelling or redness,	

Serious side effects	What to do
decreased range of motion in the joints - possible symptoms of pain and inflammation in the joints (arthritis) **Signs and symptoms of kidney problems** • Changes in the amount or colour of the urine, pain while urinating, pain in kidney area - possible symptoms of inflammation of the kidneys (nephritis) **Signs and symptoms of blood-related problems** • Bruising and bleeding (such as nosebleeds) - possible symptoms of low platelet count (immune thrombocytopenia) • A condition where the bone marrow fails to produce enough new blood cells (aplastic anaemia) which can result in anaemia (decreased red blood	

Serious side effects	What to do
cells), and susceptibility to infection or bruising **Signs and symptoms of bladder problems** • Frequent or painful urination, urge to pass urine, blood in urine, pressure in lower abdomen (inflammation of the bladder) **Signs and symptoms of immune system problems** • A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called haemophagocytic lymphohistiocytosis). Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney	

Serious side effects	What to do
abnormalities, and heart problems • A condition in which some or all of the following happen together: muscle pain or weakness, changes in eyesight, feeling tired, shortness of breath, chest pain, or irregular heartbeat (myocarditis-myositis-myasthenia gravis overlap syndrome)	

Less serious side effects

Less serious side effects	What to do
Signs and symptoms of hormone problems • Underactive thyroid gland which can cause tiredness, weight gain, skin and hair changes (hypothyroidism) • Overactive thyroid gland which can cause hyperactivity, sweating,	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
weight loss and thirst (hyperthyroidism) **Signs and symptoms of lung problems** • Cough • Difficulty breathing **Signs and symptoms of stomach and abdomen problems** • Diarrhoea **Signs and symptoms of skin problems** • Rash, itching • Skin colour changes in patches (vitiligo) **Signs and symptoms of muscle or joint problems** • Joint pain (arthralgia), muscle pain (myalgia) **Signs and symptoms of mouth problems** • Mouth sores or ulcers with gum inflammation (stomatitis) **Signs and symptoms of general problems**	

Less serious side effects	What to do
• Tiredness • Fever **Signs and symptoms of blood-related problems** • Muscle weakness and muscle spasms, palpitations or a change in your heartbeat (sign of changes in level of potassium in the blood) (hypokalaemia)	

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 TEVIMBRA contains

Active ingredient **(main ingredient)**	tislelizumab
Other ingredients **(inactive ingredients)**	Sodium citrate dihydrate Citric acid monohydrate Histadine hydrochloride monohydrate Histadine Trehalose dihydrate Polysorbate-20 Water for injections

You should not be given this medicine if you are allergic to any of these ingredients.

What TEVIMBRA looks like

TEVIMBRA concentrated solution for infusion is a clear to slightly opalescent, colourless to slightly yellow solution in a glass vial.

AUST R 391176

AUST R 524911

Who distributes TEVIMBRA

TEVIMBRA is supplied in Australia by

BeOne Medicines AUS Pty Ltd
Level 4, 275 George St
Sydney NSW 2000
Australia

Tel: 1800 512 109

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