

# TEVIMBRA®

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## 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.

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- ▼ 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.

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**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?**

- Your doctor will give you TEVIMBRA every 3 weeks.
- You will receive TEVIMBRA through an IV for about 60 minutes for your first treatment, and 30 minutes each following treatment.
- 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?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist that you are being given TEVIMBRA.</li><li>• If you miss a dose of TEVIMBRA, call your doctor right away to reschedule your appointment.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how TEVIMBRA affects you.</li></ul>

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](http://www.tga.gov.au/reporting-problems).

## TEVIMBRA®

**Active ingredient:** *tislelizumab*

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### 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.

## **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

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 is given**

- Your doctor will give you TEVIMBRA through an IV for about 60 minutes for your first treatment, and about 30 minutes each following treatment.

#### **When TEVIMBRA is given**

- You will be given TEVIMBRA every 3 weeks.
- Your doctor will decide how many treatments you need.



## **If you miss a dose**

- If you miss a dose of TEVIMBRA, call your doctor to reschedule as soon as possible.
- It is important that you do not miss a dose of this medicine.

## **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

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="202 1361 751 1464"><b>Signs and symptoms of hormone problems</b></p> <ul data-bbox="202 1503 783 2027" style="list-style-type: none"><li data-bbox="202 1503 783 1787">● Fatigue, swelling at base of the neck, pain in front of the throat - possible symptoms of thyroid inflammation (thyroiditis)</li><li data-bbox="202 1803 783 2027">● Frequent headaches, vision changes (either low vision or double vision), fatigue and/or</li></ul>	<p data-bbox="810 1361 1374 1758"><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>weakness, confusion, decreased blood pressure, dizziness - possible symptoms of inflammation of the pituitary gland (hypophysitis)</p> <p><b>Signs and symptoms of metabolism or nutrition problems</b></p> <ul style="list-style-type: none"> <li>● Increased blood sugar levels, thirst, dry mouth, frequent urination, tiredness, increased appetite with weight loss, confusion, nausea, vomiting, fruity-smelling breath, difficulty breathing and dry or flushed skin - potential symptoms of high blood sugar (hyperglycaemia)</li> <li>● High blood sugar, feeling more hungry or thirsty than normal, passing urine more often than normal - possible symptoms of diabetes mellitus</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="201 257 751 365"><b>Signs and symptoms of eye problems</b></p> <ul data-bbox="201 398 751 792" style="list-style-type: none"> <li data-bbox="201 398 751 792">• Eye redness, eye pain and swelling - possible symptoms of inflammation of the uvea, the layer beneath the white of the eyeball (uveitis)</li> </ul> <p data-bbox="201 813 751 920"><b>Signs and symptoms of lung problems</b></p> <ul data-bbox="201 954 751 1301" style="list-style-type: none"> <li data-bbox="201 954 751 1234">• Shortness of breath, cough or chest pain - potential symptoms of lung inflammation (pneumonitis)</li> <li data-bbox="201 1249 751 1301">• Difficulty breathing</li> </ul> <p data-bbox="201 1321 751 1429"><b>Signs and symptoms of nerve problems</b></p> <ul data-bbox="201 1462 751 2031" style="list-style-type: none"> <li data-bbox="201 1462 751 2031">• 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</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>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 - possible symptoms of Guillain-Barré syndrome</p> <p><b>Signs and symptoms of heart problems</b></p> <ul style="list-style-type: none"> <li>● 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)</li> <li>● Chest pain, fever, cough, palpitations - possible symptoms of inflammation of the</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>membrane around the heart (pericarditis)</p> <p><b>Signs and symptoms of stomach and abdomen problems</b></p> <ul style="list-style-type: none"> <li>● Severe upper stomach pain, nausea, vomiting, fever, tender abdomen - possible symptoms of inflammation of the pancreas (pancreatitis)</li> <li>● 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)</li> </ul> <p><b>Signs and symptoms of liver problems</b></p> <ul style="list-style-type: none"> <li>● Nausea, vomiting, loss of appetite, pain on the right side of the stomach, yellowing of the skin or the whites of the eyes, drowsiness,</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>dark-coloured urine, bleeding or bruising more easily than normal - possible symptoms of liver inflammation (hepatitis)</p> <p><b>Signs and symptoms of infusion related problems</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>Signs and symptoms of skin problems</b></p> <ul style="list-style-type: none"> <li>• Itching or peeling skin, skin sores - possible symptoms of severe skin reactions</li> <li>• Serious rash and reddening of the skin on upper body and quickly spreading to other parts,</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="245 250 782 981">blistering of the lips, eyes or mouth, skin peeling, sometimes 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).</p> <p data-bbox="201 1003 778 1111"><b>Signs and symptoms of muscle or joint problems</b></p> <ul data-bbox="201 1146 778 1899" style="list-style-type: none"> <li data-bbox="201 1146 778 1482">● Muscle pain, stiffness, weakness, chest pain, or severe tiredness - possible symptoms of muscle inflammation (myositis)</li> <li data-bbox="201 1505 778 1899">● Joint pain, stiffness, swelling or redness, decreased range of motion in the joints - possible symptoms of pain and inflammation in the joints (arthritis)</li> </ul>	



<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="204 259 746 367"><b>Signs and symptoms of kidney problems</b></p> <ul data-bbox="204 398 753 795" style="list-style-type: none"> <li data-bbox="204 398 753 795">• Changes in the amount or colour of the urine, pain while urinating, pain in kidney area - possible symptoms of inflammation of the kidneys (nephritis)</li> </ul>	

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p data-bbox="204 1126 746 1234"><b>Signs and symptoms of hormone problems</b></p> <ul data-bbox="204 1265 753 1848" style="list-style-type: none"> <li data-bbox="204 1265 753 1556">• Underactive thyroid gland which can cause tiredness, weight gain, skin and hair changes (hypothyroidism)</li> <li data-bbox="204 1568 753 1848">• Overactive thyroid gland which can cause hyperactivity, sweating, weight loss and thirst (hyperthyroidism)</li> </ul> <p data-bbox="204 1865 746 1973"><b>Signs and symptoms of lung problems</b></p>	<p data-bbox="817 1126 1375 1350"><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Cough</li> </ul> <p><b>Signs and symptoms of stomach and abdomen problems</b></p> <ul style="list-style-type: none"> <li>• Diarrhoea</li> </ul> <p><b>Signs and symptoms of skin problems</b></p> <ul style="list-style-type: none"> <li>• Rash, itching</li> </ul> <p><b>Signs and symptoms of muscle or joint problems</b></p> <ul style="list-style-type: none"> <li>• Joint pain (arthralgia), muscle pain (myalgia)</li> </ul> <p><b>Signs and symptoms of mouth problems</b></p> <ul style="list-style-type: none"> <li>• Mouth sores or ulcers with gum inflammation (stomatitis)</li> </ul> <p><b>Signs and symptoms of general problems</b></p> <ul style="list-style-type: none"> <li>• Tiredness</li> </ul>	

**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](http://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

<b>Active ingredient (main ingredient)</b>	tislelizumab
<b>Other ingredients (inactive ingredients)</b>	Sodium citrate dihydrate Citric acid monohydrate Histadine hydrochloride monohydrate Histadine Trehalose dihydrate

Polysorbate-20 Water for injections
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**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

## **Who distributes TEVIMBRA**

TEVIMBRA is supplied in Australia by

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

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