

# LIBTAYO®

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## 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.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. What is Libtayo used for?

Libtayo contains the active ingredient cemiplimab. Libtayo is an anti-cancer medicine. Libtayo is used in adults to treat types of skin cancer called advanced cutaneous squamous cell carcinoma (CSCC), and locally advanced or metastatic basal cell carcinoma (BCC), after previously receiving treatment with a hedgehog pathway inhibitor. Libtayo is also used in adults to treat advanced non-small cell lung cancer (NSCLC).

For more information, see Section [1. What is Libtayo used for?](#) in the full CMI.

## 2. What should I know before I am given Libtayo?

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

**Check with your doctor** if you have an autoimmune disease, have had an organ transplant, or you have received or plan to receive a bone marrow transplant using bone marrow from another person, or if you have lung or breathing problems, liver problems, kidney problems, diabetes, or any other medical conditions.

**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 Libtayo?](#) in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with Libtayo 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 Libtayo given?

- Libtayo will be given to you under the supervision of a doctor experienced in cancer treatment.
- Libtayo is given as a drip into a vein (intravenous infusion). The infusion will last about 30 minutes.
- Libtayo is usually given every 3 weeks.
- The information in this Leaflet can be found in the Patient Alert Card you have been given by your doctor. It is important that you keep this Patient Alert Card and show it to your partner or caregivers.

More instructions can be found in Section [4. How is Libtayo given?](#) in the full CMI.

## 5. What should I know while using Libtayo?

<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Libtayo has no or minor influence on your ability to drive and use machines.</li><li>• If you feel tired, do not drive or use machines until you feel better.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• It is unlikely that you will be asked to store Libtayo yourself. It will usually be stored in</li></ul>

the pharmacy or on the ward.

- Undiluted Libtayo will be stored in a refrigerator at 2°C to 8°C. It must not be frozen.
- Store in the original package in order to protect from light.
- Keep this medicine out of the sight and reach of children.

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

## 6. Are there any side effects?

**Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Libtayo.**

Serious side effects can include skin problems, lung problems, liver problems, symptoms of type 1 diabetes, kidney problems, infusion-related reactions and problems in other parts of the body.

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).

## LIBTAYO®

**Active ingredient:** cemiplimab

This medicine has **provisional approval** in Australia for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation, and metastatic basal cell carcinoma after previously receiving treatment with a hedgehog pathway inhibitor. The decision to approve this medicine has been made on the basis of results from clinical studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

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### Consumer Medicine Information (CMI)

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

**It is important that you keep the Patient Alert Card with you during and after treatment.**

**Where to find information in this leaflet:**

- [1. What is Libtayo used for?](#)
- [2. What should I know before I am given Libtayo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Libtayo given?](#)
- [5. What should I know while using Libtayo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. What is Libtayo used for?**

**Libtayo contains the active ingredient cemiplimab.**  
Libtayo is an anti-cancer medicine.

**Libtayo is used in adults to treat:**

- a type of skin cancer called advanced cutaneous squamous cell carcinoma (CSCC)
- a type of skin cancer called advanced basal cell carcinoma (BCC) after previously receiving treatment with a hedgehog pathway inhibitor
- a type of lung cancer called advanced non-small cell lung cancer (NSCLC).

**Libtayo works by helping your immune system fight your cancer.**

## 2. What should I know before I am given Libtayo?

### Warnings

#### You should not be given Libtayo if:

- Libtayo works by helping your immune system fight your cancer.

If you think you may be allergic, or you are not sure, talk to your doctor before you are given Libtayo.

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.

If you are not sure whether you should be given this medicine, talk to your doctor.

#### Check with your doctor if you:

- you have an autoimmune disease (a condition where the body attacks its own cells)
- you have had an organ transplant, or you have received or plan to receive a bone marrow transplant using bone marrow from another person (allogeneic hematopoietic stem cell transplant)
- you have lung or breathing problems

- you have liver problems
- you have kidney problems
- you have diabetes
- you have any other medical conditions.

If you have not told your doctor about any of the above, tell him or her before you start taking Libtayo.

If any of the above apply to you, or you are not sure, talk to your doctor or nurse before you are given Libtayo.

Libtayo can cause some serious side effects that you need to tell your doctor about immediately. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one side effect at the same time. These serious side effects include:

- Skin problems
- Lung problems (pneumonitis)
- Gut problems (colitis)
- Liver problems (hepatitis)
- Hormone gland problems - especially thyroid, pituitary, adrenal glands and the pancreas
- Type 1 diabetes
- Kidney problems (nephritis and kidney failure)
- Central nervous system problems (such as meningitis)
- Muscle problems (inflammation of the muscles called myositis)
- Infusion-related reactions
- Problems in other parts of the body (see Side effects).



Look out for these side effects while you are receiving Libtayo. See additional information under Section [6. Are there any side effects?](#) If you have any of these side effects, talk to your doctor immediately.

Your doctor may give you other medicines in order to stop more severe reactions and reduce your symptoms. Your doctor also may delay your next dose of Libtayo or stop your treatment.

## **Children and adolescents**

Libtayo should not be used in children and adolescents below 18 years of age.

## **Pregnancy**

**If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.**

Libtayo can harm your unborn baby.

**Tell your doctor immediately if you become pregnant while you are being treated with Libtayo.**

If you are able to become pregnant, you must use an effective method of contraception to avoid becoming pregnant:

- while you are being treated with Libtayo and
- for at least 4 months after the last dose.

**Talk to your doctor about the contraception methods that you must use during this time.**

## **Breastfeeding**

**If you are breast feeding or plan to breast-feed, ask your doctor for advice before you are given this medicine.**

**Do not breast feed while you are being treated with Libtayo and for at least 4 months after the last dose.**

It is not known if Libtayo passes into your breast milk.

### **3. What if I am taking other medicines?**

**Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines.**

**In particular, tell your doctor, pharmacist or nurse if you are taking or have ever taken any of the following medicines:**

- a cancer medicine called idelalisib
- medicines that make your immune system weak - examples include corticosteroids, such as prednisone. These medicines may interfere with the effect of Libtayo. However, once you are treated with Libtayo, your doctor may give you corticosteroids to reduce the side effects that you may have with Libtayo.

### **4. How is Libtayo given?**

Libtayo will be given to you under the supervision of a doctor experienced in cancer treatment.

Libtayo is given as a drip into a vein (intravenous infusion).

The infusion will last about 30 minutes.

Libtayo is usually given every 3 weeks.

## **How much you will receive**

The recommended dose of Libtayo is 350 mg.

Your doctor will decide how much Libtayo you will receive and how many treatments you will need.

Your doctor will test your blood for certain side effects during your treatment.

## **If you miss an appointment**

**Call your doctor as soon as possible to make another appointment.**

It is very important that you do not miss a dose of this medicine.

## **If you stop receiving Libtayo**

**Do not stop treatment of Libtayo unless you have discussed this with your doctor.**

This is because stopping your treatment may stop the effect of the medicine.

## **Patient Alert Card**

The information in this Leaflet can be found in the Patient Alert Card you have been given by your doctor. It is important that you keep this Patient Alert Card and show it to your partner or caregivers.

**If you have any questions about your treatment, ask your doctor.**

## **5. What should I know while using Libtayo?**

### **Driving and using machines**

Libtayo has no or minor influence on your ability to drive and use machines.

**If you feel tired, do not drive or use machines until you feel better.**

### **Storage**

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

Undiluted Libtayo will be stored in a refrigerator at 2°C to 8°C. It must not be frozen.

**Store in the original package in order to protect from light.**

**Keep this medicine out of the sight and reach of children.**

## **Disposal**

**Do not store any unused portion of the infusion solution for re use.**

Your doctor or nurse will dispose of any leftover Libtayo that is no longer needed.

## **6. Are there any side effects?**

**Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Libtayo.**

Libtayo 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 attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

Libtayo acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and may need treatment or require you to stop treatment with Libtayo. Some inflammatory conditions may also lead to death.

## **Talk to your doctor before trying to treat any of your symptoms.**

You may need periodic blood tests or other tests so that your doctor can check that your liver and kidneys are functioning as normal.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>● <b>Generalised signs and symptoms:</b></li><li>● Fatigue (feeling tired)</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 problems in other organ systems:</b></p> <ul style="list-style-type: none"><li>● Muscle or bone pain</li><li>● Diarrhoea</li><li>● Weak muscles</li><li>● Joint pain, swelling</li><li>● Inflammation of the mouth</li><li>● High blood pressure</li></ul>	<p><b>Speak to your doctors if you have any of these less serious side effects</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● Signs and symptoms of skin problems:<ul style="list-style-type: none"><li>● widespread rash or itching</li><li>● skin blistering</li><li>● ulcers in mouth or other mucous membrane.</li></ul></li><li>● Signs and symptoms of lung problems:<ul style="list-style-type: none"><li>● shortness of breath</li><li>● chest pain</li><li>● new or worsening cough</li></ul></li><li>● Signs and symptoms of problems with your intestines:<ul style="list-style-type: none"><li>● frequent diarrhoea or more bowel movements than usual</li><li>● stools that are black or tarry or have blood and mucous</li><li>● severe stomach (abdomen) pain or tenderness</li></ul></li></ul>	<p><b>If any of the following happen after you have been given Libtayo tell your doctor immediately. If you cannot reach your doctor you must seek immediate medical attention</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Signs and symptoms of liver problems:</li> <li>● severe nausea or vomiting</li> <li>● feeling less hungry than usual</li> <li>● pain on right side of your stomach</li> <li>● yellowing of your skin or the whites of your eyes</li> <li>● dark urine (the colour of tea)</li> <li>● bleeding or bruising more easily than normal</li> <li>● feeling sleepy</li> <li>● Signs and symptoms of hormone gland problems (especially the thyroid, pituitary, and adrenal glands):</li> <li>● headaches that will not go away or unusual headaches</li> <li>● fast heartbeat</li> <li>● increased sweating</li> <li>● feeling more cold or hot than usual</li> <li>● severe tiredness</li> </ul>	



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dizziness or fainting</li> <li>● weight gain or weight loss</li> <li>● feeling more hungry or thirsty than usual</li> <li>● hair loss</li> <li>● constipation</li> <li>● your voice gets deeper</li> <li>● very low blood pressure</li> <li>● urinating more often than usual</li> <li>● nausea or vomiting</li> <li>● stomach (abdomen) pain</li> <li>● changes in mood or behaviour (such as decreased sex drive, being irritable or forgetful)</li> <li>● Signs and symptoms of blood sugar problems:</li> <li>● feeling more hungry or thirsty than usual</li> <li>● needing to urinate more often</li> <li>● weight loss and feeling tired</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Signs and symptoms of kidney problems</li> <li>● change in the amount or colour of your urine</li> <li>● blood in your urine</li> <li>● swollen ankles</li> <li>● feeling less hungry than normal.</li> <li>● Signs and symptoms of infusion (IV) reactions:</li> <li>● shortness of breath or wheezing</li> <li>● chills, shaking or fever</li> <li>● itching or rash</li> <li>● flushing or swollen face</li> <li>● dizziness</li> <li>● nausea, vomiting or abdominal pain.</li> <li>● Signs and symptoms of problems in other organ systems:</li> <li>● Nervous system problems</li> <li>● headache or stiff neck</li> <li>● fever or chills</li> <li>● feeling tired or weak</li> <li>● vomiting</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● confusion, memory problems or feeling sleepy</li> <li>● fits (seizures)</li> <li>● seeing or hearing things that are not really there (hallucinations)</li> <li>● severe muscle weakness</li> <li>● tingling, numbness</li> <li>● weakness or burning pain in arms or legs</li> <li>● paralysis in the extremities</li> <li>● Muscle and joint problems</li> <li>● joint pain or swelling</li> <li>● muscle pain, weakness or stiffness</li> <li>● Eye problems</li> <li>● changes in eyesight</li> <li>● eye pain or redness</li> <li>● sensitivity to light</li> <li>● Heart and circulatory problems</li> <li>● changes in heartbeat, heart beating fast,</li> </ul>	

Serious side effects	What to do
<p>seeming to skip a beat or pounding sensation</p> <ul style="list-style-type: none"> <li>● chest pain</li> <li>● shortness of breath</li> <li>● Other:</li> <li>● dryness in many parts of the body from mouth to eyes, nose, throat and the top layers of skin</li> <li>● low red blood cells</li> <li>● bruises on the skin or bleeding</li> <li>● <b>There are possible side effects of treatment with Libtayo in people who have received a transplant:</b> <ul style="list-style-type: none"> <li>○ <b>Rejection of a transplanted organ</b></li> <li>○ <b>rejection has been reported with PD-1 inhibitors. Your doctor should tell you what signs and symptoms you should report, depending on</b></li> </ul> </li> </ul>	

Serious side effects	What to do
<p data-bbox="293 246 727 353"><b>the type of organ transplant you had</b></p> <ul data-bbox="248 371 775 591" style="list-style-type: none"> <li data-bbox="248 371 775 591">○ <b>Risk of graft-versus-host-disease (GVHD) in people with stem cell transplants</b></li> </ul> <p data-bbox="201 622 756 1303">These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, abdominal pain, and diarrhoea.</p>	

The above list includes serious side effects that may require urgent medical attention or hospitalisation.

These are not all of the possible side effects of Libtayo. Call your doctor for advice about side effects.

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

**Tell your doctor if you notice anything else that is making you feel unwell.**

## 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.

## 7. Product details

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

### What Libtayo contains

<b>Active ingredient (main ingredient)</b>	One ml of concentrate contains 50 mg of cemiplimab.  Each vial contains 350 mg cemiplimab in 7 ml of concentrate.
<b>Other ingredients (inactive ingredients)</b>	Histidine  Histidine monohydrochloride monohydrate  Proline  Sucrose

Polysorbate 80 Water for injections
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Libtayo looks like**

Libtayo concentrate for solution for infusion (sterile concentrate) is supplied as a clear to slightly opalescent, colourless to pale yellow sterile solution that may contain trace amounts of translucent to white particles.

Each carton contains 1 glass vial with 7 ml of concentrate.

LIBTAYO cemiplimab 350 mg concentrate for solution for infusion AUST R 320609

## **Who distributes Libtayo**

Libtayo is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

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