

- ▼ This medicine is subject to additional monitoring due to provisional approval. 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 .

LIBTAYO®

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. 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.

Cemiplimab

Consumer Medicine Information

What is in this leaflet

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

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

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

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

Keep this leaflet in a safe place.

You may need to read it again.

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

What Libtayo is used for

Libtayo is an anti-cancer medicine that contains the active substance cemiplimab, which is a monoclonal antibody.

Libtayo is used in adults to treat a type of skin cancer called advanced cutaneous squamous cell carcinoma, also known as CSCC.

Libtayo works by helping your immune system fight your cancer.

Before you are given Libtayo

When you must not be given Libtayo

You should not be given Libtayo if:

- you are allergic to cemiplimab or any of the other ingredients of this medicine (listed in section 6).

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.

Talk to your doctor or nurse before you are given Libtayo if:

- 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.

Look out for side effects

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 ‘Side Effects’. If you have any of these 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.

Other medicines and Libtayo

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.

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.

Breast-feeding

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.

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.

How Libtayo is given

Libtayo will be given to you in a hospital or clinic - supervised by 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.

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.

Tell your doctor as soon as possible if you notice any of the following:

- Fatigue (feeling tired)
- Muscle pain
- Diarrhoea
- Rash, itching
- Weak muscles
- Joint pain, swelling
- Inflammation of the mouth

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:

- Skin problems such as widespread rash or itching, skin blistering or ulcers in mouth or other mucous membrane.
- Lung problems (pneumonitis) such as new or worsening cough, being short of breath or chest pain.
- Gut problems (colitis) such as frequent diarrhoea often with blood or mucus, more bowel movements than usual, stools that are black or tarry, and severe stomach (abdomen) pain or tenderness.
- Liver problems (hepatitis) such as yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on right side of your stomach (abdomen), feeling sleepy,

dark urine (the colour of tea), bleeding or bruising more easily than normal and feeling less hungry than usual.

- Hormone gland problems such as headache that will not go away or unusual headaches, fast heartbeat, increased sweating, feeling more cold or hot than usual, very tired, dizzy or fainting, weight gain or weight loss, feeling more hungry or thirsty than usual, hair loss, constipation, your voice gets deeper, very low blood pressure, urinating more often than usual, nausea or vomiting, stomach (abdomen) pain, changes in mood or behaviour (such as decreased sex drive, being irritable or forgetful).
- Symptoms of type 1 diabetes such as feeling more hungry or thirsty than usual, needing to urinate more often, weight loss, and feeling tired.
- Kidney problems (nephritis and kidney failure) such as urinating less often than usual, passing blood, swollen ankles and feeling less hungry than normal.
- Infusion-related reactions (sometimes can be severe or life-threatening) such as chills, shaking or fever, itching or rash, flushing or swollen face, being short of breath or wheezing, feeling dizzy or feel like passing out and back or neck pain, nausea, vomiting or abdominal pain.
- Problems in other parts of the body such as:
 - Nervous system problems such as headache or stiff neck, fever, feeling tired or weak, chills, vomiting, confusion, memory problems or feeling sleepy, fits (seizures), seeing or hearing things that are not really there (hallucinations), severe muscle weakness,

tingling, numbness, weakness or burning pain in arms or legs, paralysis in the extremities

- Muscle and joint problems such as joint pain or swelling, muscle pain, weakness or stiffness
- Eye problems such as changes in eyesight, eye pain or redness, sensitivity to light
- Heart and circulatory problems such as changes in heartbeat, heart beating fast, seeming to skip a beat or pounding sensation, chest pain, shortness of breath
- Other: dryness in many parts of the body from mouth to eyes, nose, throat and the top layers of skin, bruises on the skin or bleeding.

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.

After you are given Libtayo

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.

Product description

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.

Ingredients

The active substance is cemiplimab:

- One ml of concentrate contains 50 mg of cemiplimab.
- Each vial contains 350 mg cemiplimab in 7 ml of concentrate.

The other ingredients are:

- Histidine
- Histidine monohydrochloride monohydrate
- Proline
- Sucrose
- Polysorbate 80
- Water for injections.

Supplier

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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infusion AUST R 320609

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