

Problems in other parts of the body

Nervous system problems

- Headache or stiff neck
- Fever
- Feeling tired or weak
- Chills
- Vomiting
- Confusion
- Memory problems or feeling sleepy
- Severe muscle weakness
- Seeing or hearing things that are not really there (hallucinations)
- Fits (seizures)
- Tingling or numbness
- Weakness or burning pain in arms or legs
- Paralysis in the extremities (hands or feet)

Muscle and joint problems

- Joint pain or swelling
- Muscle pain, weakness or stiffness

Eye problems

- Changes in eyesight
- Sensitivity to light
- Eye pain or redness
- Inflammation of the eye

Heart and circulatory problems

- 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, enlarged liver and/or spleen, lymph node enlargement
- Risk of solid organ transplant rejection

Warning message for healthcare professionals treating the patient at any time, including in conditions of emergency.

This patient has been prescribed LIBTAYO, a PD-1 blocking antibody. LIBTAYO can cause immune-related adverse reactions that affect the skin, lungs, gut, liver, hormone glands, kidneys, and other parts of the body. Early recognition and appropriate management are necessary to minimise the consequences of any adverse reactions. Refer to the LIBTAYO Product Information (PI) for details on the detection and management of any adverse reactions, available at: <https://www.tga.gov.au>.

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system at: <https://www.tga.gov.au/safety/reporting-problems>.

Important contact information

To make it easier to contact your healthcare team, write their contact details in the form below.

MY NAME

MY EMERGENCY CONTACT

MY EMERGENCY CONTACT'S PHONE NUMBER

DOCTOR/HOSPITAL/CLINIC NAME

DOCTOR/HOSPITAL/CLINIC PHONE NUMBER

You can contact the Medical Information team on 1800 566 020 or via medinfo.australia@medisonpharma.com.

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MEDISON

Patient Alert Card

LIBTAYO®(cemiplimab)

Important safety information to minimise the risks of immune-related adverse reactions

This Patient Alert Card will help you identify and report any symptoms of side effects from your treatment with LIBTAYO® (cemiplimab).

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

Read this Patient Alert Card along with the Consumer Medicine Information (CMI), available at <https://www.tga.gov.au>.

Speak to your Healthcare Professional team (doctor, nurse, pharmacist) if you would like more information or if you have any concerns or questions about your treatment with LIBTAYO.

▼ **This medicinal product is subject to additional monitoring.** This will allow quick identification of new safety information. You can help by reporting any side effects you experience. You can report side effects to your doctor, or directly at: <https://www.tga.gov.au/safety/reporting-problems>.

Important information and actions

Before you take LIBTAYO:

- Tell your doctor about all medical conditions that you have and about all medications that you are taking before you take LIBTAYO.

During treatment with LIBTAYO:

- LIBTAYO can cause serious side effects that can get worse.
- Report all symptoms of side effects to your doctor, even if they are not listed in this Patient Alert Card.
- Do not delay in reporting all symptoms of side effects to your doctor, even if you are away from home.
- Do not attempt to treat any of these symptoms yourself without first consulting your treating doctor.
- Carry this Patient Alert Card with you at all times during the course of your treatment.
- Show this Patient Alert Card to any doctor you see other than the doctor who prescribed you LIBTAYO.

Look out for these side effects while you are receiving LIBTAYO. If you have any of these effects, or if they get worse, talk to your doctor immediately.

In the case of an emergency, call 000 or seek urgent medical attention from your closest hospital or emergency department.

Skin problems

- Widespread rash or itching
- Skin blistering
- Ulcers in mouth or other mucous membrane

Lung problems (pneumonitis)

- New or worsening cough
- Being short of breath
- Chest pain

Gut (intestines or stomach) problems

- Frequent diarrhoea or more bowel movements than usual
- Stools that are black or tarry or have blood and mucus
- Severe stomach (abdomen) pain or tenderness
- coeliac disease (characterised by symptoms such as stomach pain, diarrhoea and bloating after consuming gluten-containing foods)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency)

Liver problems (hepatitis)

- 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
- Feeling less hungry than usual

Hormone gland problems

- Headache that will not go away or unusual headaches
- Fast heartbeat
- Increased sweating
- Feeling more cold or hot than usual
- Severe tiredness
- Dizziness 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 or diabetic ketoacidosis

- Feeling more hungry or thirsty than usual
- Needing to urinate more often
- Stomach pain
- Weight loss
- Feeling tired or sick
- Fast and deep breathing
- Confusion or unusual sleepiness
- A sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat

Kidney problems (nephritis and kidney failure)

- Urinating less often than usual
- Passing blood when you urinate
- Swollen ankles
- Feeling less hungry than normal

Infusion-related reactions (sometimes can be severe or life-threatening)

- Chills
- Shaking or fever
- Itching or rash
- Flushing or swollen face
- Nausea
- Vomiting
- Back or neck pain
- Abdominal pain
- Being short of breath or wheezing
- Feeling dizzy or like passing out