

## Important safety information to minimise complications from any immune-related adverse reactions

This Patient Guide will help you identify and report any symptoms of side effects from your treatment with LIBTAYO<sup>®</sup> (cemiplimab).

- It is important that you read this booklet even if you have been taking LIBTAYO for a while.
- This is because it contains the most up to date information on your medicine.
- Keep this booklet. You may need to read it again.

**Read this booklet along with the Consumer Medicine Information (CMI), available [here](#).**

You can also request a copy by contacting our Medical Information team on 1800 566 020 or [medinfo.australia@medisonpharma.com](mailto:medinfo.australia@medisonpharma.com).

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 Guide.
- 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 the Patient Alert Card (provided separately) with you at all times during the course of your treatment.
- Show the 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
- Feeling sleepy
- Dark urine (the colour of tea)
- Bleeding or bruising more easily than normal
- Feeling less hungry than usual

### **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 mucous
- 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)

### **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
- Being short of breath or wheezing
- Feeling dizzy or like passing out
- Back or neck pain
- Nausea
- Vomiting
- Abdominal pain

## 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
  - Fits (seizures)
  - Seeing or hearing things that are not really there (hallucinations)
  - Severe muscle weakness
  - 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
  - Eye pain or redness
  - Sensitivity to light
  - 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

### 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's name \_\_\_\_\_

Doctor's phone number \_\_\_\_\_

Hospital/clinic name \_\_\_\_\_

Hospital/clinic phone number \_\_\_\_\_

Other important contacts/numbers \_\_\_\_\_

You can contact the Medison Medical Information team on 1800 566 020  
or via [medinfo.australia@medisonpharma.com](mailto:medinfo.australia@medisonpharma.com).

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