

## Patient Guide

# LIBTAYO<sup>®</sup>

(cemiplimab)

## Important safety information to minimize complications from immune-mediated adverse reactions

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

### Important information

- Tell your doctor about all medical conditions that you have and about all medications that you are taking before you take LIBTAYO.
- LIBTAYO can cause serious side effects that can get worse.
- Report all side effects to your doctor, even if they are not listed in this Patient Guide.
- Do not delay in reporting all side effects to your doctor, even if you are away from home.
- Do not attempt to treat any of these side effects yourself without first consulting your doctor.
- Carry the Patient Alert Card with you at all times during treatment.
- Show the Patient Alert Card to all doctors you see other than the doctor who prescribed you LIBTAYO.

LIBTAYO contains an active substance cemiplimab which is anti-PD-1 monoclonal antibody. LIBTAYO works by helping your immune system fight your cancer. LIBTAYO acts on your immune system and may cause inflammation in parts of your body.

## Seek urgent medical attention if you have any of the following signs or symptoms, or if they get worse:

### Skin problems

- 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 problems (colitis)

- Frequent diarrhoea often with blood or mucus
- More bowel movements than usual
- Stools that are black or tarry
- Severe stomach (abdomen) pain or tenderness

### 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
- 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
- Passing water 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
- Weight loss
- Feeling tired or feeling sick
- Stomach pain
- Fast and deep breathing
- Confusion
- 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)**

- Passing water less often than usual
- Passing blood
- 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 feel 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, numbness, weakness or searing pain in the arms or legs
- Paralysis of the extremities
- 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
- Heart and circulation problems
  - Changes in heartbeat, beating fast or seeming to skip a beat or a pounding sensation
  - Chest pain
  - Shortness of breath
- Other
  - Dryness in many parts of the body, from the 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.

## Important contact information

Doctor's name \_\_\_\_\_

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

Patient's name \_\_\_\_\_

Patient's phone number \_\_\_\_\_

Emergency contact's phone number \_\_\_\_\_

For further information, consult the Patient Information Leaflet (PIL)  
or call Sanofi at 09-8633081

Reporting suspected adverse reactions to the Ministry of Health  
by using an online form <https://sideeffects.health.gov.il>.  
Also report directly to Sanofi Company 09-8633081

This Patient guide was approved according to the guidelines of Ministry of Health on  
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Sanofi and Regeneron are collaborating in the global development and commercialization for LIBTAYO® (cemiplimab).  
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