

Patient Guide

LIBTAYO

(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® (cemiplimab).

For further information, consult the Patient Information Leaflet (PIL).

The guide is written in the masculine language for convenience only but is intended for both genders.

This guide was approved according to the guidelines of the Ministry of Health in February 2024

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 diarrhea 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 color 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 behavior (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 odor 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 limbs

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 _____

Reporting side effects

In case of any side effects (including any side effects not listed in the Patient Information leaflet), please refer to the attending physician or to the pharmacist.

By reporting side effects, you can help provide more information about the safety of this medication.

Side effects can be reported to the Ministry of Health via the portal for the report of side effects on the homepage of the Ministry of Health website: www.health.gov.il

Or by clicking on the link: <https://sideeffects.health.gov.il/>.

In addition, side effects can be reported to Medison Pharma Ltd.
at email: PVIsrael@medisonpharma.com or at fax no: 03-9234218

REGENERON

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