

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).

Detailed information on this medicine is available on Malta Authority web site <https://medicinesauthority.gov.mt/> For further information, consult the Patient Information Leaflet (PIL) at or call Sanofi Medical Information at informazioni.medicoscientifiche@sanofi.com

Please keep your Libatyo Patient Card

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Report any side effects to the Medicines Authority using the **online side effect report form** or filling in the Adverse Drug Reactions reporting form, which is available online at www.medicinesauthority.gov.mt/adrportal and sending it to The Medicines Authority Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta or via e-mail to postlicensing.medicinesauthority@gov.mt Alternatively to Sanofi Srl at PharmacovigilanceMalta@sanofi.com

Malta

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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 burning pain in arms or legs
- Paralysis in 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 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

Important contact information

Doctor's name _____

Doctor's phone number _____

My name _____

My phone number _____

My emergency contact _____

Emergency contact's phone number _____



Sanofi and Regeneron are collaborating in the global development and commercialization for LIBTAYO® (cemiplimab).

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