

Patient Guide

LIBTAYO▼ (cemiplimab)

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

This Patient Guide will help you identify and report any symptoms of side effects from your treatment with cemiplimab.

For further information including additional copies of this Patient Guide, the Patient Alert Card and/or the patient information leaflet (PIL) visit: www.medicines.org.uk/emc or contact Sanofi Medical Information at Tel: 0845 372 7101 or e-mail: UK-medicalinformation@sanofi.com.

Important information

- The purpose of this guide is to help inform you about the possible side effects associated with cemiplimab, known as immune-related adverse reactions.
- Tell your doctor about all medical conditions that you have and about all medications that you are taking before you take cemiplimab.
- Cemiplimab can cause serious side effects that can get worse.
- **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 doctor.**
- **Carry the Patient Alert Card with you at all times during and after treatment with cemiplimab, at the direction of your doctor.**
- **Show the Patient Alert Card to all doctors you see other than the doctor who prescribed you cemiplimab.**
- **You can report suspected adverse drug reactions directly via your local regulatory authority (see below for side effect reporting information).**

▼ 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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via: Tel: 0800 0902314 or e-mail: UK-drugsafety@sanofi.com.

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

Skin problems (inflammation of the skin, possibly fatal)

- Rash or itching
- Skin blistering and/or peeling
- Ulcers in mouth or other mucous membrane e.g. in lining of nose, throat, or genital area

Lung problems (inflammation of the lungs)

- 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 (inflammation of the liver)

- 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 (especially thyroid, pituitary, adrenal)

- Headache that will not go away or unusual headaches
- Fast heartbeat
- Increased sweating
- Feeling cold
- 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)

Type 1 diabetes

- Feeling more hungry or thirsty than usual
- Needing to urinate more often
- Weight loss
- Feeling tired

Kidney problems (inflammation of the kidney)

- Passing water less often than usual
- Passing blood
- Swollen ankles
- Feeling less hungry than normal

Infusion 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

Other organs

- Eyes: sudden changes in eyesight, eye pain, irritation, itchiness or redness
- Muscles: pain or weakness
- Heart: changes in heartbeat such as beating fast or seeming to skip a beat or a pounding sensation, shortness of breath, feeling tired, or chest pain
- Blood: bruises on the skin or bleeding
- Nerves: inflammation that causes pain, tingling, numbness, weakness or paralysis in the arms and legs
- Brain: inflammation usually caused by infection (e.g. meningitis) causing severe headache or stiff neck, high temperature or fever, feeling tired or weak, confusion or feeling delirious, memory problems or feeling sleepy, fits (seizures), sensitivity to light

Patient Alert Card

Card to be carried at all times. Show this Patient Alert Card to all doctors you see other than the doctor who prescribed you cemiplimab.

