Important contact information

Doctor's name

Doctor's phone number

My name

My phone number

My emergency contact

Emergency contact's phone number

REGENERON

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

Additional symptoms

- Eye problems: changes in eyesight, eye pain, redness, or sensitivity to light
- Muscle and joint problems: joint pain or swelling, muscle pain, weakness or stiffness
- Heart and circulatory problems: changes in heartbeat such as beating fast or seeming to skip a beat or a pounding sensation, shortness of breath or chest pain
- Blood: bruises on the skin or bleeding
- 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
- Other: dryness in many parts of the body from mouth to eyes, nose, throat and the top layers of skin, enlarged liver and/or spleen, lymph node enlargement

Warning message for healthcare professionals treating the patient at any time, including in conditions of emergency

This patient has been prescribed cemiplimab, a PD-1 blocking antibody, which can cause immune-mediated adverse reactions that affect the skin, lungs, gut, liver, hormone glands, kidneys, and other parts of the body. These can occur at any time during treatment or months after discontinuation. Early recognition and appropriate management are necessary to minimise the consequences of any adverse reactions. Refer to the cemiplimab Summary of Product Characteristics for details on the detection and management of any adverse reactions. The most up to date version of the Summary of Product Characteristics can be accessed on www.medicines.ie

Patient Card

LIBTAYO® (cemiplimab)

Important safety information to minimise the risks of immune-mediated adverse reactions

This Patient Card will help you identify and report side effects from your treatment with cemiplimab. For further information including additional copies of this Patient Card, and/or the patient information leaflet (PIL) visit: www.yourmedicines.ie
or contact Regeneron via: 1800 800 920
or medical.information_global@regeneron.com

Please report any side effects to:
HPRA Pharmacovigilance. Website: www.hpra.ie.
Adverse events should also be reported to Regeneron on Tel: 1800 800 920.
Alternatively, send via email to medical.information_global@regeneron.com.

Important information

- 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.
- Report all side effects to your doctor, even if they are not listed in this Patient Card.
- 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 this Patient Card with you at all times during and after treatment with cemiplimab, at the direction of your doctor.
- Show this Patient Card to all doctors you see other than the doctor who prescribed you cemiplimab.

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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 e.g. in lining of nose, throat, or genital area

Lung problems

- New or worsening cough
- Being short of breath
- Chest pain

Gut problems

- 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

- 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 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

- 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
- Nausea
- Vomiting
- Abdominal pain