

MEDICATION GUIDE
LIBTAYO® (Lib-TIE-oh)
(cemiplimab-rwlc)
injection

What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat a type of skin cancer by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:

Lung problems (pneumonitis). Signs and symptoms of pneumonitis may include:

- new or worsening cough
- shortness of breath
- chest pain

Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include:

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

Liver problems (hepatitis). Signs and symptoms of hepatitis may include:

- yellowing of your skin or the whites of your eyes
- drowsiness
- severe nausea or vomiting
- dark urine (tea colored)
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal
- feeling less hungry than usual

Hormone gland problems (especially the adrenal glands, pituitary, thyroid, and pancreas). Signs and symptoms that your hormone glands are not working properly may include:

- headache that will not go away or unusual headaches
- feeling cold
- rapid heart beat
- constipation
- increased sweating
- your voice gets deeper
- extreme tiredness
- very low blood pressure
- weight gain or weight loss
- urinating more often than usual
- dizziness or fainting
- nausea or vomiting
- feeling more hungry or thirsty than usual
- stomach-area (abdomen) pain
- hair loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems, including nephritis and kidney failure. Signs of these problems may include:

- decrease in your amount of urine
- swelling in your ankles
- blood in your urine
- loss of appetite

Skin problems. Signs of these problems may include:

- rash
- skin blistering
- itching
- painful sores or ulcers in mouth or nose, throat, or genital area

Problems in other organs. Signs of these problems may include:

- headache
- seeing or hearing things that are not there (hallucinations)
- tiredness or weakness
- severe muscle weakness
- sleepiness
- low red blood cells (anemia)
- changes in heartbeat, such as beating fast, or seeming to skip a beat, or pounding sensation
- bruises on the skin or bleeding
- changes in eyesight
- confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, or seizures (encephalitis)
- swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain (sarcoidosis)

Rejection of a transplanted organ. Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

Infusion (IV) reactions that can sometimes be severe and life-threatening. Signs of these problems may include:

- chills or shaking
- fever
- itching or rash
- feel like passing out
- flushing
- back or neck pain
- shortness of breath or wheezing
- facial swelling
- dizziness

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with LIBTAYO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may delay or completely stop treatment with LIBTAYO if you have severe side effects.

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What is LIBTAYO?

LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

It is not known if LIBTAYO is safe and effective in children.

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have had an organ transplant
- have lung or breathing problems
- have liver or kidney problems
- have diabetes
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby.

Females who are able to become pregnant:

- o Your healthcare provider will give you a pregnancy test before you start treatment with LIBTAYO.
- o You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of LIBTAYO. Talk to your healthcare provider about birth control methods that you can use during this time.
- o Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO.
- are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LIBTAYO?

- Your healthcare provider will give you LIBTAYO into your vein through an intravenous (IV) line over 30 minutes.
- LIBTAYO is usually given every 3 weeks.
- Your healthcare provider will decide how many treatments you will need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of LIBTAYO?

LIBTAYO can cause serious side effects, including:

- See "What is the most important information I should know about LIBTAYO?"

The most common side effects of LIBTAYO include tiredness, rash and diarrhea.

These are not all the possible side effects of LIBTAYO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LIBTAYO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about LIBTAYO, talk with your healthcare provider. You can ask your healthcare provider for information about LIBTAYO that is written for health professionals.

What are the ingredients of LIBTAYO?

Active ingredient: cemiplimab-rwlc

Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, sucrose, L-proline, Polysorbate 80, and Water for Injection, USP.

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Manufactured by: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707 U.S. License No. 1760
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