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 certain types of cancers 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. You can have more than one of these problems at the same time. 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 new or worsening signs or symptoms, including:

- **Lung problems.**
  - cough
  - shortness of breath
  - chest pain
- **Intestinal problems.**
  - 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.**
  - yellowing of your skin or the whites of your eyes
  - severe nausea or vomiting
  - pain on the right side of your stomach-area (abdomen)
- **Hormone gland problems.**
  - headache that will not go away or unusual headaches
  - eye sensitivity to light
  - eye problems
  - rapid heartbeat
  - increased sweating
  - extreme tiredness
  - weight gain or weight loss
  - feeling more hungry or thirsty than usual
  - dark urine (tea colored)
  - bleeding or bruising more easily than normal
- **Kidney problems.**
  - decrease in your amount of urine
  - blood in your urine
  - swelling of your ankles
  - low red blood cells, bruising
- **Skin problems.**
  - rash
  - itching
  - skin blistering or peeling
  - painful sores or ulcers in mouth or nose, throat, or genital area
  - your voice gets deeper
  - changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
  - fever or flu-like symptoms
  - swollen lymph nodes

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms which may include:

- chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- fever
- back or neck pain
- facial swelling
- headache that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- dark urine (tea colored)
- bleeding or bruising more easily than normal
- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- low red blood cells, bruising
- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in mouth or nose, throat, or genital area
- your voice gets deeper
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- fever or flu-like symptoms
- swollen lymph nodes

Infusion reactions that can sometimes be severe. Signs and symptoms of infusion reactions may include:

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

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

Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with LIBTAYO. Your healthcare provider will monitor you for these complications.

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 also need to delay or completely stop treatment with LIBTAYO if you have severe side effects.

What is LIBTAYO?
LIBTAYO is a prescription medicine used to treat:
- people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC). LIBTAYO may be used to treat CSCC that has spread or cannot be cured by surgery or radiation.
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 received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with LIBTAYO. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of LIBTAYO. 
- If you 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.

What will happen during treatment with LIBTAYO?

- LIBTAYO is given by a nurse or other qualified health professional through a vein in your arm or hand. 
- If you receive LIBTAYO by a vein in your arm or hand, you may feel pain or see a purplish discoloration in your hand or arm. 
- LIBTAYO is usually given every 3 weeks.

How will I receive LIBTAYO?

- Your healthcare provider will give you LIBTAYO into your vein through an intravenous (IV) line over 30 minutes.
- 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.

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

The most common side effects of LIBTAYO when used alone include:

- muscle or bone pain
- tiredness
- hair loss
- muscle or bone pain
- nausea
- rash
- diarrhea
- tiredness
- numbness, pain, tingling or burning in your hands or feet
- decreased appetite

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.