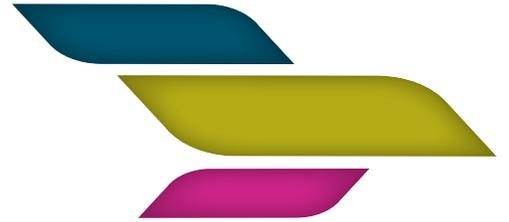


What you may expect from treatment with LIBTAYO

Understanding the serious and most common side effects of treatment



You may experience side effects while on treatment with LIBTAYO. You can have more than one problem at the same time. Side effects can happen anytime during your treatment or even after your treatment has ended. An important part of your treatment is working with your healthcare team to understand the side effects and how to identify if you are experiencing any.

In this brochure, you will learn about the signs and symptoms of the serious and most common side effects associated with treatment with LIBTAYO. Your healthcare provider may do blood tests to check you for side effects.

Please keep in mind, side effects can differ from person to person, so everyone's treatment experience with LIBTAYO will be different. These are not all the possible side effects of LIBTAYO. Talk to your doctor for medical advice about side effects.

LIBTAYO can cause serious side effects, including those described in this brochure.

These problems can sometimes become severe or life-threatening and can lead to death. Getting medical treatment right away may help keep these problems from becoming more serious.

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) 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.

Important Safety Information

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

LIBTAYO is a medicine that may treat certain 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.

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)

Content is consistent with the Oncology Nursing Society (ONS) Standards and Guidelines. The ONS Seal of Approval does not constitute medical advice and does not imply product endorsement by ONS. Healthcare providers should exercise their own independent medical judgment. Website content or other resources referenced in these materials have not been reviewed for the ONS Seal of Approval.



What is the 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 problem 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 symptoms of the following problems or these symptoms get worse during or after your treatment with LIBTAYO.**

Getting medical treatment right away may help 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.



Lung problems

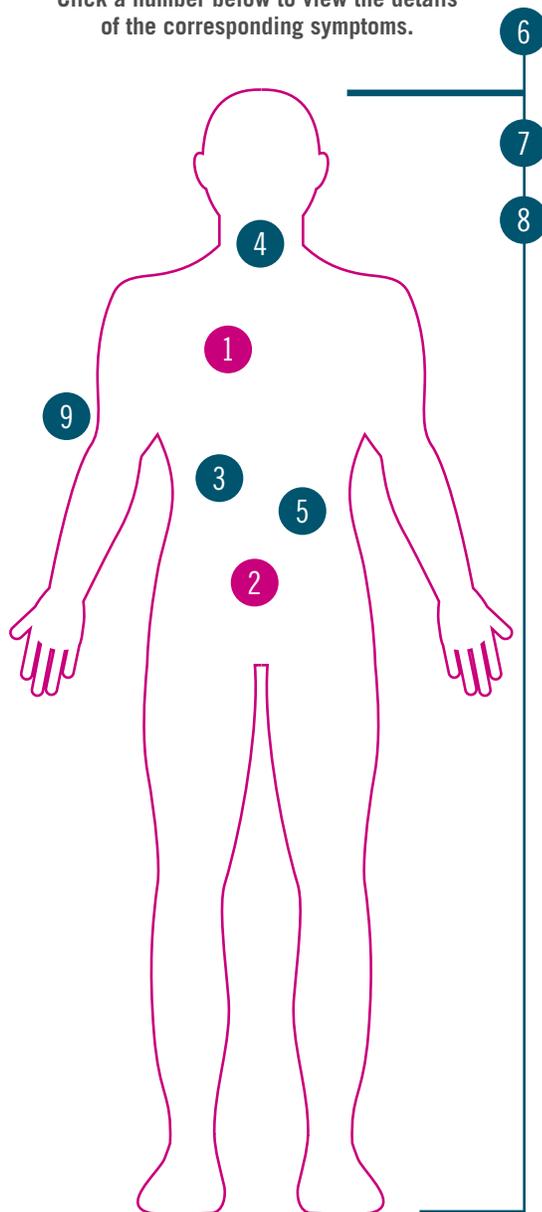
- Cough
- Shortness of breath
- Chest pain



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

Click a number below to view the details of the corresponding symptoms.



Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)



Liver problems

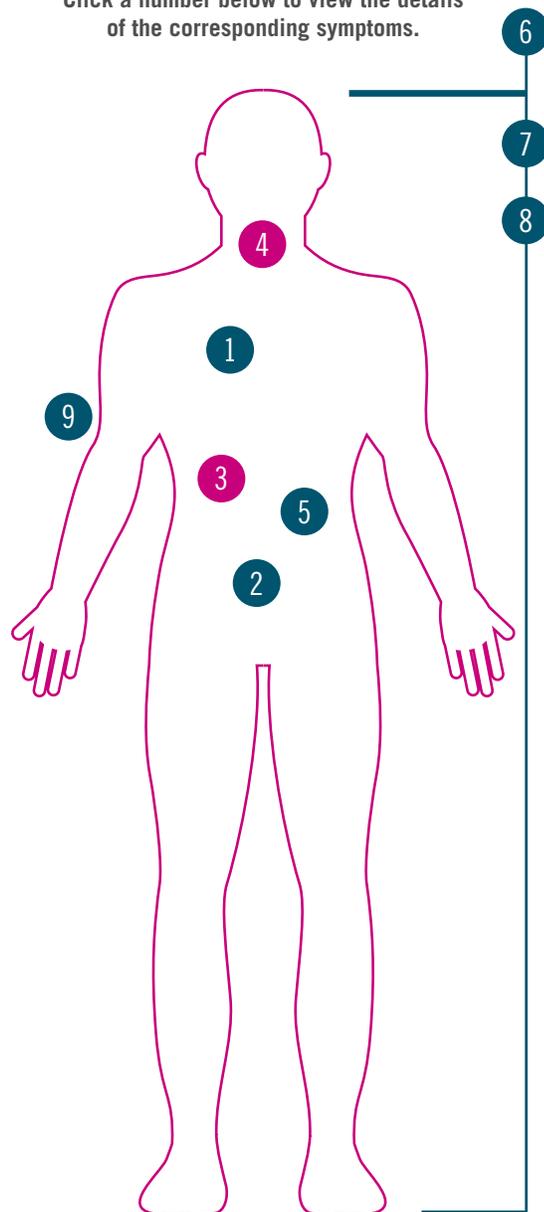
- Yellowing of your skin or the whites of your eyes
- Severe nausea or vomiting
- Pain on the right side of your stomach area (abdomen)
- Dark urine (tea colored)
- Bleeding or bruising more easily than normal



Hormone gland problems

- Headaches 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
- Urinating more often than usual
- Hair loss
- Feeling cold
- Constipation
- Your voice gets deeper
- Dizziness or fainting
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Click a number below to view the details of the corresponding symptoms.



Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

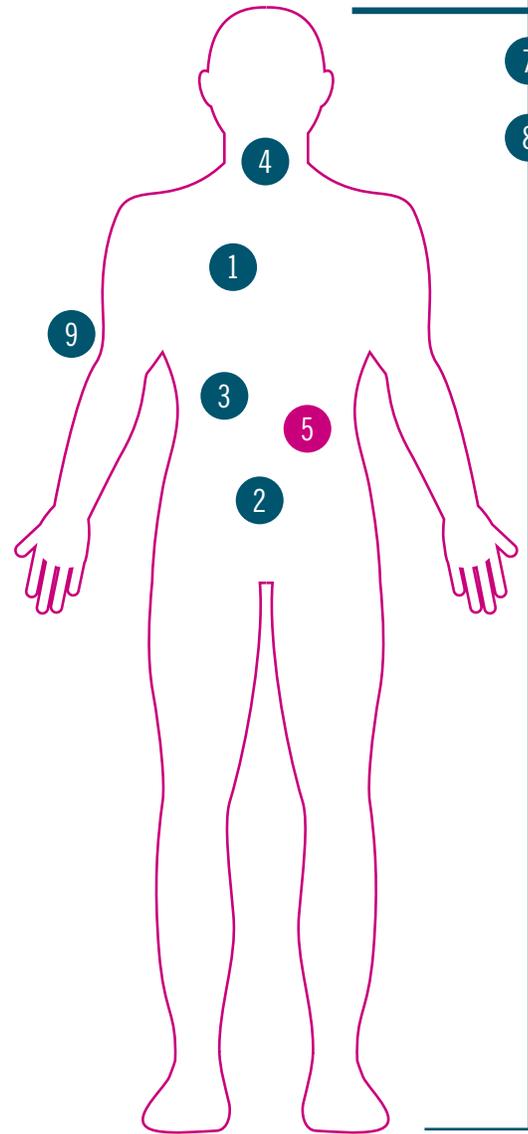
- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach-area (abdomen) pain or tenderness

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)



Click a number below to view the details of the corresponding symptoms.

- 6
- 7
- 8



Kidney problems

- Decrease in your amount of urine
- Blood in your urine
- Swelling of your ankles
- Loss of appetite



Skin problems

- Rash
- Itching
- Skin blistering or peeling
- Painful sores or ulcers in the mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **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), dark urine (tea colored), or bleeding or bruising more easily than normal
- **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, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)



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



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
- Low red blood cells, bruising



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.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite
- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)



Side effects in the LIBTAYO study

The most commonly reported side effects of LIBTAYO were **muscle or bone pain, tiredness, rash, and diarrhea**. These are not all of the possible side effects of LIBTAYO.

In 2 LIBTAYO clinical trials of 219 patients with advanced CSCC, the most common side effects reported were:

- **74 out of 219 patients (34%) experienced tiredness**
- **68 out of 219 patients (31%) experienced rash**
- **55 out of 219 patients (25%) experienced diarrhea**
- **53 out of 219 patients (24%) experienced muscle or bone pain**
- **46 out of 219 patients (21%) experienced nausea**
- **39 out of 219 patients (18%) experienced itching**
- **31 out of 219 patients (14%) experienced a cough**
- **28 out of 219 patients (13%) experienced constipation**
- **24 out of 219 patients (11%) experienced joint pain**
- **24 out of 219 patients (11%) experienced anemia (low red blood cell count)**
- **22 out of 219 patients (10%) experienced vomiting**
- **22 out of 219 patients (10%) experienced hypothyroidism (underactive thyroid)**
- **22 out of 219 patients (10%) experienced a loss of appetite**

Please keep in mind that side effects can differ from person-to-person, so everyone's treatment experience with LIBTAYO will be different.

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

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)

 **LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg

Additional information about LIBTAYO

What is the active ingredient of LIBTAYO?

Active ingredient: cemiplimab-rwlc

How will I receive LIBTAYO?

LIBTAYO is a 350-mg intravenous (IV) infusion given for 30 minutes, every 3 weeks. That means it enters the body through a vein, and is administered at a hospital or healthcare facility. Your healthcare provider will decide how many treatments you will need. Your doctor may perform blood tests to check you for side effects.

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 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.
- 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.
- 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.



It is important to continue treatment as prescribed by your doctor. If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).

 **LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **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, low red blood cells, or bruising
- **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, or 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.

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

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- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- 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

Please see additional Important Safety Information throughout and [click here for full Prescribing Information, including Medication Guide.](#)



Patient wallet card

[Click here](#) to download your printable wallet card and carry it with you while you are on treatment with LIBTAYO. If you see a healthcare provider who is not involved in your cancer treatment, such as a primary care provider or a doctor in the emergency room, show the care team this card to alert them that you are taking LIBTAYO. This information is important for all healthcare providers involved in your care.

To learn more, visit LIBTAYO.com

Important Safety Information (continued)

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

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time
- 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.

The most common side effects of LIBTAYO include muscle or bone pain, 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. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

Please [click here for full Prescribing Information](#), including [Medication Guide](#).



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