



For patients with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation

LIBTAYO works with your immune system to help treat advanced CSCC

Patient portrayal.

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](#).

Understanding your treatment with LIBTAYO

Your treatment team has given you this brochure because you have been prescribed or are considering treatment with LIBTAYO. The information in this brochure is not meant to take the place of talking with your doctor, nurse, or other healthcare providers. Always talk with your doctor if you have any questions about your treatment or any side effects.

As you begin your treatment, there can be a lot of information and many details to keep track of. This guide was designed to help you understand your treatment with LIBTAYO, which treats people with a type of skin cancer called cutaneous (kyoo-TAY-nee-us) squamous (SKWAY-mus) cell carcinoma (sel KAR-sih-NOH-muh) (CSCC) that has spread or cannot be cured by surgery or radiation. It provides you with questions you can ask your doctor, along with plenty of space to take notes during your conversation.

This guide will provide you with important information, including:

- Information to help you understand CSCC and how it may become advanced
- The ways advanced CSCC can be treated
- Information about LIBTAYO, including what you can expect from treatment and the resources that are available to you while you are taking LIBTAYO

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
- **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

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



CSCC

Learn about a type of skin cancer called cutaneous squamous cell carcinoma (CSCC), and what it means when it grows and becomes advanced.

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

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

CSCC

TREATING ADVANCED CSCC

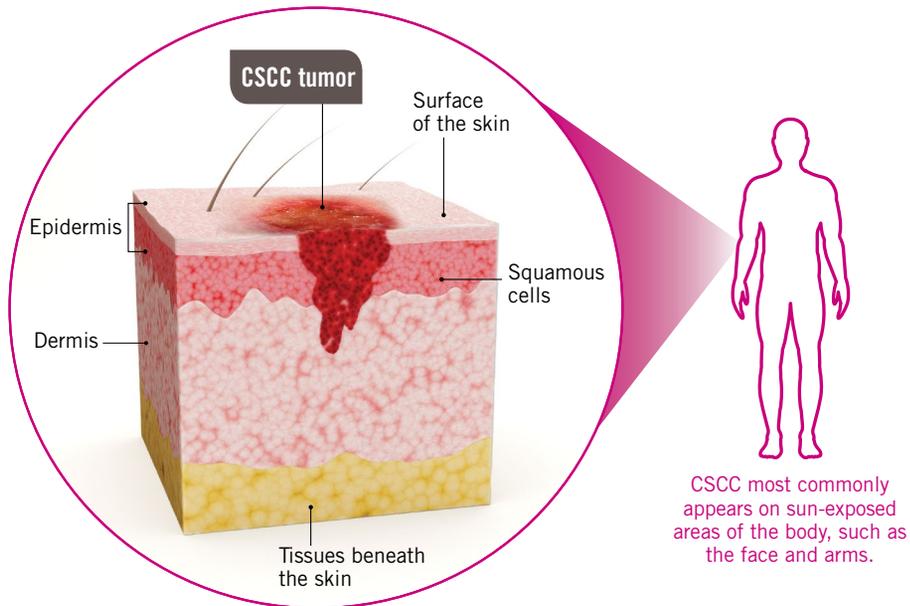
TREATMENT WITH LIBTAYO

What is CSCC?

Cutaneous squamous cell carcinoma (CSCC) is the second most common type of skin cancer in the United States. CSCC starts in squamous cells, which are a type of flat, thin cell in the top layer of the skin (the top layer of the skin is known as the epidermis).

CSCC develops when squamous cells go through changes called mutations in their DNA. A cell's DNA contains instructions that tell a cell what to do. The mutations tell the squamous cells to grow out of control and to continue living and dividing when normal cells would die, which can result in tumor development. Most of the DNA mutations in these skin cells are caused by ultraviolet exposure from sunlight and in tanning lamps and tanning beds.

CSCC can appear as scaly red patches, open sores, rough, thickened, or wart-like skin, or raised growths with a central depression.



Most CSCC cases, about 95%, may be easily treated and curable when detected early. CSCC cases that become advanced can be more challenging to treat successfully.

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

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

What is advanced CSCC?

CSCC that has spread extensively or aggressively, or in some cases has not responded to multiple treatments and has returned repeatedly, is considered advanced because it has spread or cannot be cured by surgery or radiation.

- There are 2 forms: metastatic CSCC and locally advanced CSCC
- Metastatic CSCC occurs when tumors spread beyond their original location to other parts or organs of the body
- Locally advanced CSCC occurs when tumors become large or have grown deep into underlying tissues, muscles, or nerves, destroying nearby healthy tissue. These lesions can become swollen, painful, and disfiguring



CSCC can have different appearances and can vary from person to person. CSCC grows as a lesion on the surface of the skin. It may also grow in other parts of the body and can even spread inside the body.

Important Safety Information (continued)

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

- **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
- **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](#).



Questions for your doctor

Below are questions you can ask your doctor to understand your advanced CSCC better. Use this page to take notes during your conversation.

How is advanced CSCC different from other types of skin cancers?

How do I know if I have metastatic CSCC or locally advanced CSCC?

How do you determine if someone with advanced CSCC cannot be cured by surgery or radiation?

Important Safety Information (continued)

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

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



Treating advanced CSCC

This next section provides an overview of the types of doctors who treat advanced CSCC and some of the treatment options that may be appropriate for you.



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



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

Who treats advanced CSCC?

The following specialized doctors may be involved in your care and can help determine the right treatment options for you.

- **Medical oncologists:** Doctors who diagnose and treat cancers
- **Surgical oncologists:** Doctors with specialized training to manage and remove tumors and other cancerous tissue through surgery
- **Radiation oncologists:** Doctors who specialize in radiation therapy, a treatment that uses high doses of radiation to kill cancer cells and shrink tumors
- **Dermatologists:** Doctors who evaluate and treat disorders of the skin
- **Mohs surgeons:** Doctors who use a specific surgical technique, called Mohs surgery, to treat skin cancer. They remove thin layers of cancerous skin until no cancer cells remain



If possible, it is important that your doctor considers working with a team of multidisciplinary healthcare providers when helping you look at all of your treatment options, and that they work together to develop a treatment plan specific to you.

Important Safety Information (continued)

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

- **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

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



How can advanced CSCC be treated?

While most CSCC cases can be cured with surgery or radiation when found and treated early, in advanced stages these can become more difficult to treat successfully.



Surgery

During surgery, the intent is to remove the cancerous tumor and affected surrounding tissue. Some people with advanced CSCC may have multiple surgeries as part of their treatment to remove tumors on the head, neck, and other parts of the body. Depending on the extent and location of the surgery, some may need reconstructive surgery to repair areas of the skin or other structures of the body such as the nose or ear affected by the tumor. Surgery for CSCC is typically performed by a surgical oncologist, Mohs surgeon, or another trained surgical specialist.



Radiation

Advanced CSCC may also be treated with radiation therapy, which is a type of cancer treatment that uses beams of intense energy, most often X-rays, to kill cancer cells and shrink tumors. Radiation therapy is given by a radiation oncologist.

Immunotherapy may also be used to treat metastatic CSCC or locally advanced CSCC when it cannot be cured by surgery or radiation.



Immunotherapy

Immunotherapy is a form of systemic drug therapy (a type of drug that moves through the body) that may help your immune system fight cancer. Your body might not attack cancer because the cancer cells have developed ways to avoid the immune system. Immunotherapy helps the immune system recognize, attack, and kill the cancer cells. Immunotherapy is given by an oncologist. It is not chemotherapy, which is another type of systemic drug therapy.

Immunotherapy can cause your immune system to attack normal organs and tissues in your body, which may cause serious side effects.



Some advanced CSCC tumors may not be cured by surgery or radiation.

Important Safety Information (continued)

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.

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

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

Questions for your doctor

Below are questions you can ask your doctor to help you make an informed decision about treatment. Use this page to take notes during your conversation.

Who are the members of my healthcare team and what are their roles?

How did you determine that I could not be cured by surgery or radiation?

How did you determine that immunotherapy is right for me?

Important Safety Information (continued)

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

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



Starting treatment with LIBTAYO

You and your doctor have decided that treatment with LIBTAYO is the next step. This section will help you understand:

- What LIBTAYO is
- How it works with your immune system to help treat advanced CSCC
- How patients with metastatic CSCC or locally advanced CSCC who could not be cured by surgery or radiation were treated with LIBTAYO in clinical trials
- How you will receive treatment with LIBTAYO
- What you can expect from treatment, including the possible side effects

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

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

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is the first medicine approved by the Food and Drug Administration (FDA) to treat CSCC that has spread or cannot be cured by surgery or radiation. LIBTAYO is a type of immunotherapy called a programmed death receptor-1 (PD-1) inhibitor. LIBTAYO is not chemotherapy or radiation therapy.

LIBTAYO may be right for people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that:



Has spread to other parts of the body (metastasized)

AND



Cannot be cured by surgery or radiation

Important Safety Information (continued)

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

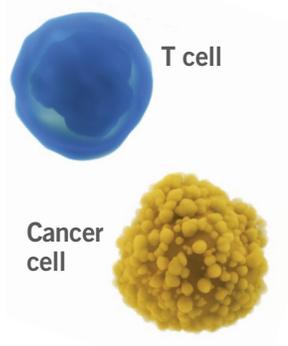
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby

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

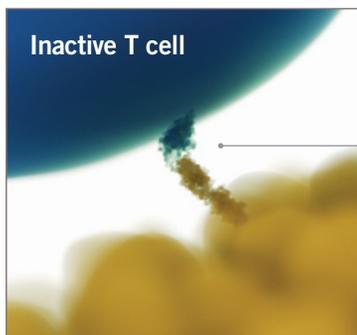
**LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO may help your immune system fight advanced CSCC

Your immune system defends your body against disease.



Certain white blood cells (**T cells**) are an important part of your immune system. Their job is to find and fight infections and kill **cancer cells**. T cells have a protein on the cell surface called **PD-1**, or programmed death receptor-1, which is involved in normal T-cell function.



Some cancer cells are able to trick the immune system to prevent the attack from T cells. **When proteins on cancer cells bind to the PD-1 receptor on T cells, this binding makes the T cell inactive and stops it from killing the cancer cell.**

PD-1 receptor binding to the cancer cell protein

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

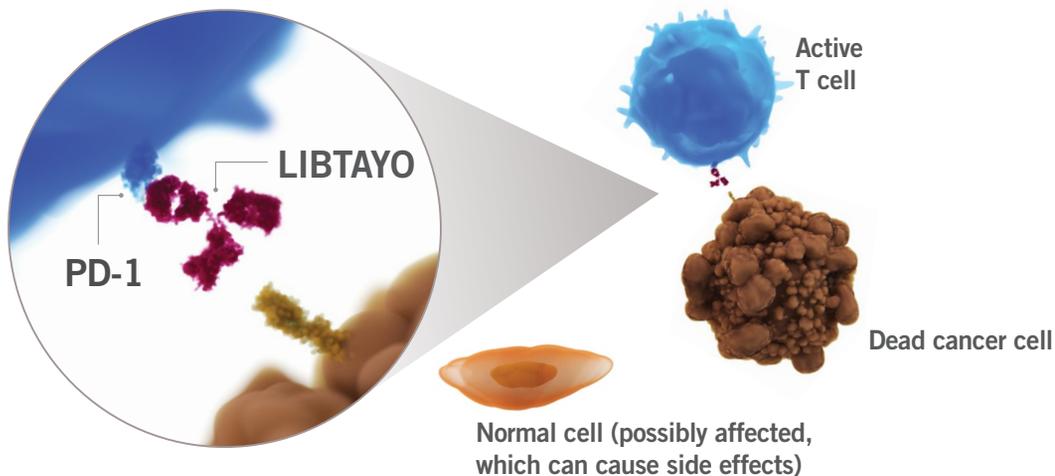
Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).

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

LIBTAYO works with your immune system to help treat advanced CSCC (continued)

LIBTAYO is a treatment that works by blocking PD-1 receptors to inhibit binding with the cancer cell protein. The T cell then remains active, so it can attack and kill the cancer cell.

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.



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 (continued):

- 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

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

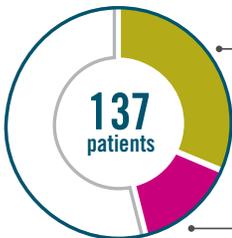
**LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg

LIBTAYO study results

LIBTAYO helped shrink tumors in some clinical trial patients.

In 1 clinical trial of 137 patients with CSCC that had spread or could not be cured by surgery or radiation treated with LIBTAYO*:

63 out of 137 patients (46%) saw an improvement in their advanced CSCC with LIBTAYO



Of these patients,

43 out of 137 patients (31%)
saw tumors shrink (partial response)

20 out of 137 patients (15%)
saw tumors disappear completely (complete response)

- In 50 out of 63 patients (79%) who responded to LIBTAYO, the response lasted 6 months or longer
- In 34 out of 63 patients (54%) who responded to LIBTAYO, the response lasted 12 months or longer

*Patients were dosed by body weight.

LIBTAYO may not work for everyone.

Important Safety Information (continued)

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

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

LIBTAYO study results (continued)

In the same clinical trial, in a separate group of 56 patients with CSCC that had spread who took LIBTAYO at the recommended dose*:

- **23 out of 56 patients (41%) saw an improvement in their advanced CSCC**
 - **20 out of 56 patients (36%)** saw tumors shrink (partial response)
 - **3 out of 56 patients (5%)** saw tumors disappear completely (complete response)
 - **In 15 out of 23 patients (65%)** who responded to LIBTAYO, the response lasted 6 months or longer

In a different clinical trial of 26 patients with CSCC that had spread or could not be cured by surgery or radiation†:

- **13 out of 26 patients (50%) saw tumors shrink (all partial responses)**
 - **In 11 out of 13 patients (85%)** who responded to LIBTAYO, the response lasted 6 months or longer

In these trials, responses lasted between 1 month and more than 2 years (24.2+ months); plus sign (+) denotes ongoing at last assessment.

*LIBTAYO 350 mg over a 30-minute infusion every 3 weeks.

†Patients were dosed by body weight.

LIBTAYO may not work for everyone.

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](#).

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

LIBTAYO achieved results you can see

Below is an example of a patient's response to treatment in clinical trials with LIBTAYO. **Individual patient responses may vary.**

Patient example 1

This is an example from the 31% (43 out of 137 patients) of patients who achieved a partial response in clinical trials with LIBTAYO.*

Pictured below is a neck lesion from an 85-year-old male patient. He had CSCC that had spread, or metastasized, to other parts of his body.

Before starting treatment



After 8 weeks



After 56 weeks



This patient's response was still ongoing at time of data collection.

*Patients were dosed by body weight

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](#).

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

LIBTAYO achieved results you can see (continued)

Below is an example of a patient's response to treatment in clinical trials with LIBTAYO. **Individual patient responses may vary.**

Patient example 2

This is an example from the 31% (43 out of 137 patients) of patients who achieved a partial response in clinical trials with LIBTAYO.*

Pictured below is an ear tumor from a 57-year-old male patient. He had CSCC that could not be cured by surgery or radiation.

Before starting treatment



After 24 weeks



After 88 weeks



This patient's response was still ongoing at time of data collection.

*Patients were dosed by body weight

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

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

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

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.

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)
- Dark urine (tea colored)
- Bleeding or bruising more easily than normal

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)

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
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

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 mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

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.

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)

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:

- 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

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



What are the possible side effects of LIBTAYO?

- **LIBTAYO can cause serious side effects**, including those described on pages 19 to 22 and in the Medication Guide
- 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

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



Questions for your doctor

Below are questions you can ask your doctor to better understand treatment with LIBTAYO, including possible side effects. Use this page to take notes during your conversation.

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

Are there tips you can offer to help manage side effects from LIBTAYO?

What treatment goals do you have for me with LIBTAYO?

What should I expect from treatment with LIBTAYO?

Important Safety Information (continued)

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

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



How will I receive LIBTAYO?

LIBTAYO is a medicine prescribed by a doctor. It is given in a hospital or clinic as a 30-minute intravenous (IV) infusion. That means it enters the body through a vein.

What is the schedule for infusions of LIBTAYO?



- LIBTAYO is an IV infusion (350 mg) given over 30 minutes
- Treatment with LIBTAYO happens once every 3 weeks
- Infusion reactions may happen while you are receiving the drug. Infusion reactions can sometimes be severe. Signs of these problems 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, and facial swelling. Tell your doctor right away if you start to experience any of these symptoms
- Your healthcare provider will decide how many treatments you will need
- Your healthcare provider will do blood tests to check you for side effects



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 discuss your treatment plan.

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

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

Information about infusions with LIBTAYO

Below are questions you can ask your doctor to help you prepare for your treatments with LIBTAYO.

What is the most important information I should know about my first infusion?

Is there anything you need to know from me prior to my first infusion?

Is there any type of follow-up after each infusion?

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
- **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

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



LIBTAYO Surround[®] Patient Support Program



LIBTAYO Surround is here to help. Your doctor is your trusted source for information about your condition and treatment. LIBTAYO Surround may be able to provide you with resources and support to assist you.



LIBTAYO Surround Commercial Copay Program*

You may be eligible to pay as little as \$0 per month with the LIBTAYO Surround Commercial Copay Program.



LIBTAYO Surround Patient Assistance Program†

You may be eligible to receive LIBTAYO at no cost.



Other resources

LIBTAYO Surround can help you look for other ways to afford your medicine.



Nurse support

Nurse Advocates are available whenever you need more information and to support you throughout your treatment journey.



To enroll, talk to your doctor or call LIBTAYO Surround at 1.877.LIBTAYO (1.877.542.8296), select option 1, or visit LIBTAYO.com.

*This program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, Veterans Affairs/Department of Defense, TRICARE, or similar federal or state programs. Not a debit card program. The program does not cover or provide support for supplies, procedures, or any physician-related service associated with LIBTAYO. General non-product-specific copays, coinsurance, or insurance deductibles are not covered. Additional program conditions may apply.

†Additional criteria for financial need apply.

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



LIBTAYO Patient Starter Kit

Starting a new treatment is not always easy. That is why we created the **LIBTAYO Patient Starter Kit** to help support you as you begin your treatment. The materials provided are not meant to replace the advice from your doctor. Always speak with your doctor about any questions you have about treatment with LIBTAYO.

LIBTAYO Patient Starter Kit includes the following items:

LIBTAYO patient brochure: In this brochure, you will find information about treatment with LIBTAYO and other helpful resources.



LIBTAYO Surround® patient overview brochure: If you are eligible, LIBTAYO Surround may help you with financial support for LIBTAYO.

Messenger bag: Whether you are going about your day or heading to an appointment, you can use this bag to carry all the items you need.

Blue Lizard® sunscreen: This sunscreen can help protect you from harmful UV rays.

Blue Lizard is a registered trademark of Crown Laboratories, Inc.

Travel blanket: This versatile blanket can be rolled up into a pillow or even an arm rest.

Various magazines: Read the inspirational stories of other people managing this disease. Learn about their personal victories and struggles.

LIBTAYO 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.



Order your **FREE** starter kit today!
Call LIBTAYO Surround at 1.877.LIBTAYO
(1.877.542.8296), select option 1,
Monday–Friday, 8:00 AM–8:00 PM Eastern Time.

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

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

Additional resources

Advocacy organizations give not only information, but also encouragement. There are a number of organizations that support patients with cancer and their caregivers. The organizations listed here deal with all types of cancers, including skin cancers.



The Skin Cancer Foundation

Established in 1979, the Foundation is the only global organization solely devoted to the prevention, early detection, and treatment of skin cancer. They strive to decrease the incidence of skin cancer through public and professional education and research. Visit the website to learn more about CSCC and advanced CSCC. For more information, visit: skincancer.org



American Cancer Society

The American Cancer Society is a global grassroots force of 1.5 million volunteers dedicated to saving lives, celebrating lives, and leading the fight for a world without cancer. From breakthrough research to free lodging near treatment, a 24/7/365 live helpline, free rides to treatment, and convening powerful activists to create awareness and impact, the Society is the only organization attacking cancer from every angle. For more information, visit: cancer.org



CANCERCare®

Over 75 Years of Help and Hope

CancerCare

CancerCare is the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. Their services include case management, counseling, support groups, educational workshops, publications, and more. For more information, visit: cancer.org



Cancer Support Community

The Cancer Support Community is the largest professionally led nonprofit network of cancer support worldwide. This global network is dedicated to helping all people impacted by cancer. In addition to producing educational resources, the Cancer Support Community conducts cutting-edge research on the psychological, financial, and emotional journey of cancer patients. For more information, visit: cancersupportcommunity.org



Skin Cancer Education and Research Foundation (SCERF)

SCERF is dedicated to fighting the epidemic of nonmelanoma skin cancer through awareness, resources, and support. The Foundation is committed to assisting patients, their families, and their caregivers to obtain the best care and outcomes possible, as they navigate their journey with skin cancer. Visit the website to learn more about prevention, diagnosis, and treatment of squamous cell skin cancer and basal cell carcinoma. For more information, visit: skincancerinfo.org

The inclusion of the independent nonprofit organizations listed above does not imply endorsement of LIBTAYO, Regeneron, or Sanofi Genzyme.

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

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.



In patients with CSCC that has spread or cannot be cured by surgery or radiation

LIBTAYO works with your immune system to help treat advanced CSCC

- In 1 clinical trial of 137 patients,* **almost half (63 out of 137 patients [46%])** saw an improvement in their advanced CSCC
- In the same trial, in a separate group of 56 patients with CSCC that had spread who took LIBTAYO at the recommended dose,† **23 out of 56 patients (41%)** saw an improvement in their advanced CSCC
- In this trial, responses lasted between approximately 2 months and more than 2 years (24.2+ months); plus sign (+) denotes ongoing at last assessment
- 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.

*Patients were dosed by body weight.

†LIBTAYO 350 mg over a 30-minute infusion every 3 weeks.

LIBTAYO may not work for everyone.

For more information, visit [LIBTAYO.com](https://www.libtayo.com)

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](#).

REGENERON | SANOFI GENZYME 

© 2021 Regeneron Pharmaceuticals, Inc., and sanofi-aventis U.S. LLC. All rights reserved. LIB.20.08.0086 03/21