



For patients with a type of skin cancer called basal cell carcinoma (BCC) that cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog inhibitor (HHI), or cannot receive treatment with an HHI

LIBTAYO works with your immune system to help treat locally advanced BCC

Patient portrayal.

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is a prescription medicine used to treat people with a type of skin cancer called basal cell carcinoma that cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog pathway inhibitor (HHI), or cannot receive treatment with an HHI.

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 basal (bas-al) cell carcinoma (sel KAR-sih-NOH-muh) that cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog inhibitor (HHI), or are not appropriate for an HHI. It provides you with suggested questions you can ask your doctor, along with plenty of space to take notes during your conversation.

This guide will also provide you with important information, including:

- Information to help you understand BCC and how it may become locally advanced
- The ways locally advanced BCC can be treated and the types of doctors who treat it
- 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

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BCC

Learn about a type of skin cancer called basal cell carcinoma (BCC), and what it means when it grows and becomes locally advanced.



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Patient and caregiver portrayals.

BCC

TREATING LOCALLY ADVANCED BCC

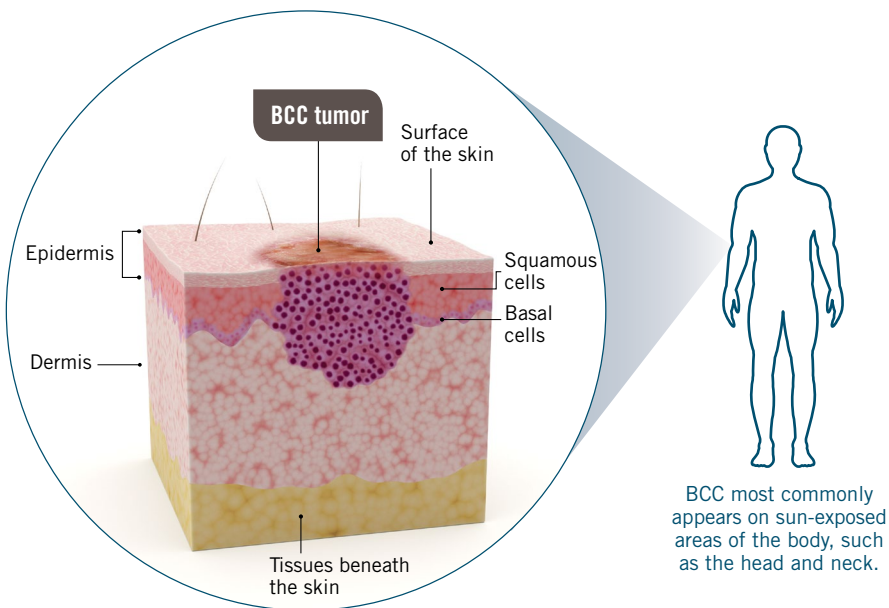
TREATMENT WITH LIBTAYO

What is BCC?

BCC is the most common type of skin cancer in the United States. BCC starts in basal cells, which are a type of cell at the bottom of the top layer of skin (known as the epidermis).

BCC develops when basal 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 basal 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 these abnormal skin cells are caused by ultraviolet exposure from sunlight, and in tanning lamps and tanning beds.

BCC can appear as open sores, red patches, pink growths, shiny bumps, scars or growths with slightly raised, rolled edges, and/or a central depression. Sometimes, the lesions may ooze, crust, itch or bleed.



Because BCC grows slowly, most cases are curable and cause minimal damage when caught and treated early. However, when BCC progresses to advanced disease, it can be challenging to treat successfully.

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(cemiplimab-rwlc)
Injection 350 mg

What is locally advanced BCC?

Locally advanced BCC is considered locally advanced when tumors become large or have grown deep into the skin, underlying tissues, muscles, or nerves, destroying nearby healthy tissue. These lesions can become swollen, painful, and disfiguring. Locally advanced BCC makes up approximately 95% of advanced BCC cases.



Locally advanced BCC can have different appearances and can vary from person to person. Locally advanced BCC grows as a lesion on the surface of the skin, and may spread and grow wide and deep into the skin.

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

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Questions for your doctor

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

How is locally advanced BCC different than other types of skin cancer?

How do I know if I have locally advanced BCC?

Why is it important to continue treating my locally advanced BCC?

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

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Treating locally advanced BCC

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

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Patient portrayal.

BCC

TREATING LOCALLY ADVANCED BCC

TREATMENT WITH LIBTAYO

Who treats locally advanced BCC?

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

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



It is important that your doctor considers working with a team of multidisciplinary healthcare providers 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

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How is locally advanced BCC treated?

While most cases of BCC 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 locally advanced BCC may have multiple surgeries as part of their treatment in order to remove tumors on the head, neck, and other parts of the body. Surgery for BCC is typically performed by a Mohs surgeon or another trained surgical specialist.



Radiation

Locally advanced BCC 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.

Systemic therapies are drugs that move through the body to treat cancer cells wherever they may be.



Hedgehog Inhibitor (HHI)

An HHI is a type of targeted therapy used to treat locally advanced BCC that has come back following surgery or radiation or that cannot be treated with surgery or radiation. HHIs work to stop cancer cells from growing and multiplying, and help shrink tumors.



Immunotherapy

Immunotherapy 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. This treatment is given by an oncologist.

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



Some locally advanced BCC tumors may need more treatment after HHIs. Ask your doctor if immunotherapy may be appropriate for you.

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 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 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 HHIs are no longer appropriate for me?

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
- 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

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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 LIBTAYO works with your immune system to treat locally advanced BCC
- Results from the LIBTAYO clinical trial
- How you will receive treatment with LIBTAYO
- What you can expect from treatment, including the possible side effects

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Patient portrayal.

What is LIBTAYO?

LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called BCC that:



Cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog inhibitor (HHI), or cannot receive treatment with an HHI

LIBTAYO is a type of immunotherapy—not chemotherapy or radiation therapy.

I was taking an HHI. Now what?

Some patients who may have tried HHIs cannot stay on treatment because it stops working and their tumors grow again, or they have side effects from taking the drug.

For people who have tried an HHI, LIBTAYO could be the next treatment option prescribed by your doctor for locally advanced BCC.

LIBTAYO and HHIs are both systemic therapies, which are drugs that move through the body to treat locally advanced BCC. Systemic therapies include treatments like chemotherapy, targeted drugs (for example, HHIs), and immunotherapy (for example, LIBTAYO).

LIBTAYO is an immunotherapy given through an infusion that may help your immune system recognize, attack, and kill the cancer cells. Your body might not attack cancer because the cancer cells have developed ways to avoid the immune system. This treatment is given by an oncologist.

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

Important Safety Information (continued)

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

- 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

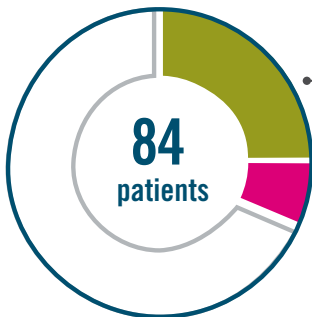
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LIBTAYO helped shrink tumors in some clinical trial patients

In a clinical trial which included patients with locally advanced BCC who had been previously treated with HHIs:

24 out of 84 patients (29%) saw an improvement in their locally advanced BCC with LIBTAYO



Of these patients,

19 out of 84 patients (23%)
saw tumors shrink (partial response)

5 out of 84 patients (6%)
saw tumors disappear completely (complete response)

- In **19 out of 24 patients (79.2%)** who responded to LIBTAYO, their response lasted at least 6 months or longer
- These patients had responses that lasted between 2.1 months and 21.4+ months; plus sign [+] means this patient was still responding to treatment at their last assessment

For patients with locally advanced BCC who have received or are not appropriate for HHIs, their doctors may recommend LIBTAYO.

Important Safety Information (continued)

Females who are able to become pregnant (continued):

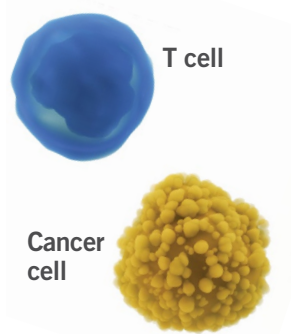
- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO

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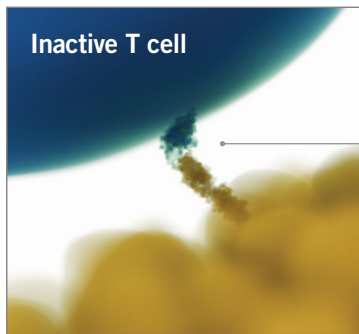
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(cemiplimab-rwlc)
Injection 350 mg

For patients who have tried an HHI or who cannot receive treatment with an HHI,
LIBTAYO may help your immune system
fight locally advanced BCC

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):

- 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

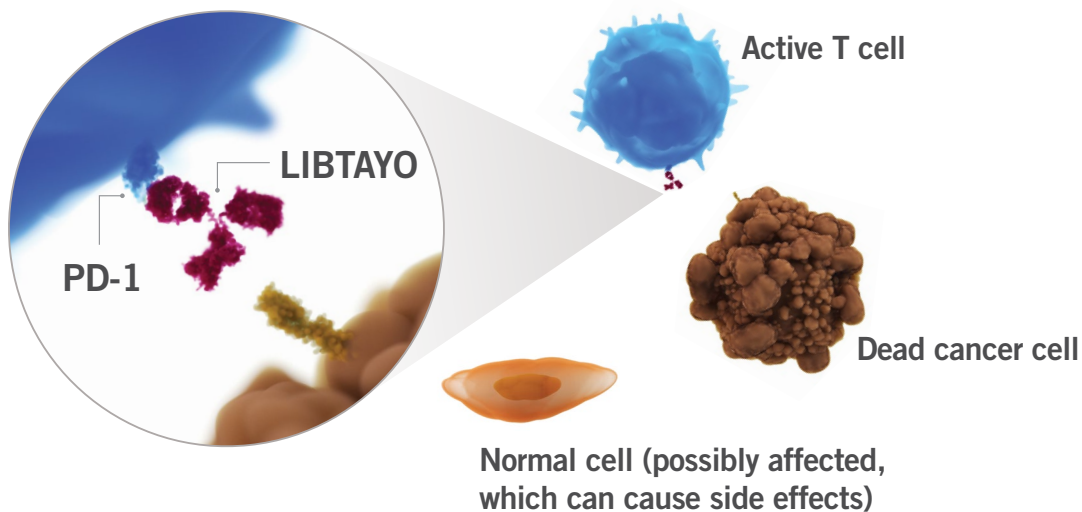
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For patients who have tried an HHI or who cannot receive treatment with an HHI,
LIBTAYO may help your immune system
fight locally advanced BCC (continued)

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)

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

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Injection 350 mg

Treatment results with LIBTAYO

From a clinical trial of patients with locally advanced BCC previously treated with an HHI

This is an example of one of the patients with locally advanced BCC previously treated with an HHI, who saw tumors shrink (partial response) with treatment. In this trial, 23% (**19 out of 84**) patients had a partial response with LIBTAYO. Individual patient responses may vary.

Patient example 1

Pictured below is a head lesion of a 66-year-old male patient.

Before starting treatment



After 9 weeks



After 18 weeks



After 101 weeks



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

Important Safety Information (continued)

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.

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Treatment results with LIBTAYO

From a clinical trial of patients with locally advanced BCC previously treated with an HHI

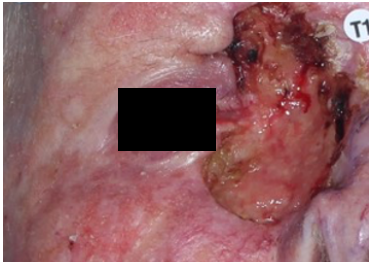
This is an example of one of the patients with locally advanced BCC previously treated with an HHI, who saw tumors shrink (partial response) with treatment. In this trial, 23% (19 out of 84) patients had a partial response with LIBTAYO. Individual patient responses may vary.

Patient example 2

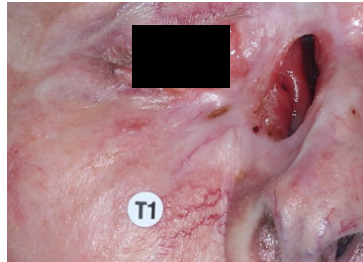
Pictured below is a facial lesion of a 77-year-old female patient.

The patient had a response that lasted almost 5 months, after which the disease worsened (as shown in the 92-week image, below).

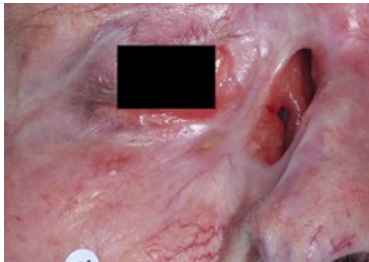
Before starting treatment



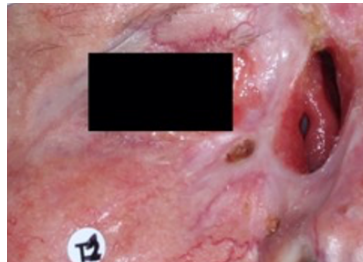
After 36 weeks



After 44 weeks



After 92 weeks



Important Safety Information (continued)

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.

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

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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

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

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

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

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 18-21 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 the LIBTAYO clinical trial,* which included patients with locally advanced BCC previously treated with an HHI, the most common side effects were:

- | | | |
|---|---|---|
| • 65 out of 132 patients (49%) experienced tiredness | • 20 out of 132 patients (15%) experienced infection of the nose, throat, and/or airways | • 16 out of 132 patients (12%) experienced a UTI (urinary tract infection) |
| • 44 out of 132 patients (33%) experienced muscle or bone pain | • 19 out of 132 (14%) experienced a loss of appetite | • 16 out of 132 patients (12%) experienced headaches |
| • 33 out of 132 patients (25%) experienced diarrhea | • 17 out of 132 patients (13%) experienced anemia (low red blood cell count) | • 15 out of 132 patients (11%) experienced constipation |
| • 29 out of 132 patients (22%) experienced having a rash | • 16 out of 132 patients (12%) experienced nausea | • 15 out of 132 patients (11%) experienced shortness of breath |
| • 26 out of 132 patients (20%) experienced itching | | • 15 out of 132 patients (11%) experienced high blood pressure |

***84 out of 132 patients in the trial had locally advanced BCC.**

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(cemiplimab-rwlc)
Injection 350 mg

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 are the side effects that can occur while taking 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:

- **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

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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?

1) 350 mg IV infusion



2) For 30 minutes



3) Every 3 weeks



- 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):

- **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 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.



For more information, call LIBTAYO Surround at **1.877.LIBTAYO (1.877.542.8296)**, select option 1, Monday–Friday, 8:00 AM–8:00 PM Eastern Time.

*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 and 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](#).

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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 BCC and advanced BCC. 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

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 organizations listed above are independent nonprofit organizations. Their inclusion here does not imply endorsement of LIBTAYO, Regeneron, or Sanofi Genzyme.

LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called basal cell carcinoma that cannot be removed by surgery (locally advanced BCC) and have received treatment with a hedgehog pathway inhibitor (HHI) or cannot receive treatment with an HHI.

For patients who have been treated with an HHI or for whom an HHI is not appropriate,
Help your immune system fight locally advanced BCC

In a clinical trial which included patients with locally advanced BCC who had been previously treated with HHIs:

24 out of 84 patients (29%)

saw an improvement in their locally advanced BCC with LIBTAYO

- These patients had responses that lasted between 2.1 months and 21.4+ months; plus sign [+] means this patient was still responding to treatment at their 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.

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](#).