



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

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



Patient and caregiver portrayals.

What type of medicine is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is an immunotherapy. Immunotherapy is a form of systemic drug therapy (a type of drug that moves through the body) that helps the immune system recognize, attack, and kill the cancer cells. LIBTAYO is not chemotherapy or radiation therapy.

LIBTAYO may be right to treat people with a type of skin cancer called advanced basal cell carcinoma (BCC) that cannot be removed by surgery (locally advanced BCC), after they have received treatment with a hedgehog pathway inhibitor (HHI), or if they cannot receive treatment with an HHI.

I was taking an HHI. Now what?

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 cancer cells wherever they may be in the body. Systemic therapies include treatments like chemotherapy, targeted drugs (for example, HHIs), and immunotherapy (for example, LIBTAYO). Treatments like these, used to attack cancer, are given by an oncologist.

The information in this fact sheet is not meant to replace talking with your doctor, nurse, or other healthcare providers. Always talk to your doctor if you have any questions about your treatment or any side effects.

Important Safety Information

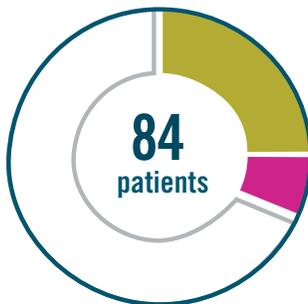
What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat certain types of skin cancer by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. 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 to see full Prescribing Information, including Medication Guide.](#)

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 [+] denotes ongoing at 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)

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
- **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 to see full Prescribing Information, including Medication Guide.](#)

How does LIBTAYO work?

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 hide from 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.

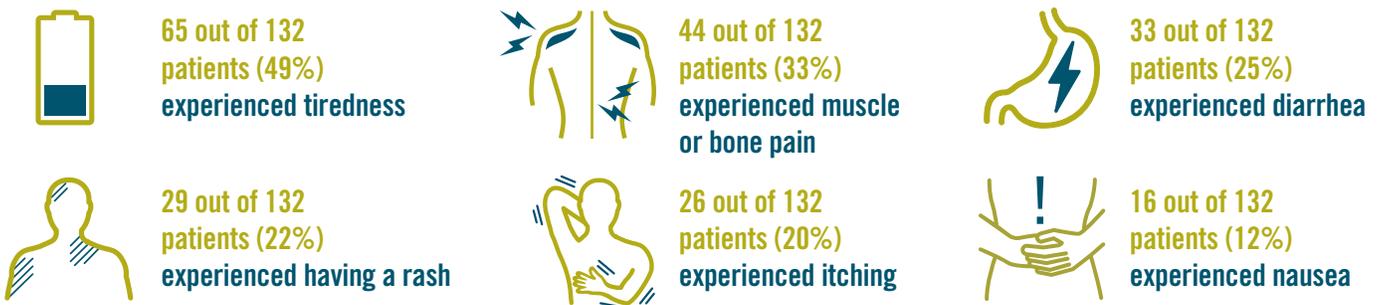
LIBTAYO is a treatment that works by blocking PD-1, to stop binding with the cancer cell protein. The T cell then remains active, so it can attack and kill the cancer cell.

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.

What are the most common side effects of LIBTAYO?

LIBTAYO can cause serious side effects, including those described in the Important Safety Information throughout and in the [Medication Guide](#). The most common side effects you may experience with LIBTAYO include tiredness, rash, diarrhea, muscle or bone pain, nausea, and itching. These are not all the possible side effects of LIBTAYO.

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



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



Please review “What is the most important information I should know about LIBTAYO?” in the [Medication Guide](#). Getting medical treatment right away may help keep these problems from becoming more serious.

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 to see 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?

1) 350 mg IV infusion



2) For 30 minutes



3) Every 3 weeks



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.

LIBTAYO Surround[®] Patient Support Program



LIBTAYO Surround may be able to provide you with resources and support throughout your treatment with LIBTAYO. LIBTAYO Surround offers information on financial assistance programs and nurse support.

To enroll, talk to your doctor or call LIBTAYO Surround at 1.877.LIBTAYO (1.877.542.8296), select option 1, Monday-Friday, 8:00 AM-8:00 PM Eastern Time, or visit LIBTAYO.com.

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: 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.

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

Important Safety Information (continued)

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

- **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:

- 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
- have diabetes;
- 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.

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 tiredness, rash, diarrhea, muscle or bone pain, nausea, and itching. 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](#).



Talk to your doctor if you think LIBTAYO may be right for you. For more information, visit [LIBTAYO.com](https://www.libtayo.com).