

Package leaflet: Information for the patient

LIBTAYO® 350 mg concentrate for solution for infusion

cemiplimab

REGENERON

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Is this leaflet hard to see or read?
Phone 0800 917 7120 for help

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- It is important that you keep the Patient Alert Card with you during treatment.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LIBTAYO is and what it is used for
2. What you need to know before you are given LIBTAYO
3. How you are given LIBTAYO
4. Possible side effects
5. How to store LIBTAYO
6. Contents of the pack and other information

1. What LIBTAYO is and what it is used for

LIBTAYO is an anti-cancer medicine that contains the active substance cemiplimab, which is a monoclonal antibody.

LIBTAYO is used in adults to treat:

- a type of skin cancer called advanced cutaneous squamous cell carcinoma (CSCC).
- a type of skin cancer called advanced basal cell carcinoma (BCC) for which you have received treatment with a hedgehog pathway inhibitor and this treatment did not work well or was not well tolerated.
- a type of lung cancer called advanced non-small cell lung cancer (NSCLC).
- a type of cancer called cervical cancer that has worsened on or after chemotherapy.

LIBTAYO may be given in combination with chemotherapy for NSCLC. It is important that you also read the package leaflets for the specific chemotherapy you may be receiving. If you have any questions about these medicines, ask your doctor.

LIBTAYO works by helping your immune system fight your cancer.

2. What you need to know before you are given LIBTAYO

You should not be given LIBTAYO if:

- you are allergic to cemiplimab or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, or you are not sure, talk to your doctor before you are given LIBTAYO.

Warnings and precautions

Talk to your doctor or nurse before you are given LIBTAYO if:

- you have an autoimmune disease (a condition where the body attacks its own cells)
- you have had an organ transplant, or you have received or plan to receive a bone marrow transplant using bone marrow from another person (allogeneic haematopoietic stem cell transplant)
- you have lung or breathing problems
- you have liver problems
- you have kidney problems

- you have diabetes
- you have any other medical conditions.

If any of the above apply to you, or you are not sure, talk to your doctor or nurse before you are given LIBTAYO.

Look out for side effects

LIBTAYO can cause some serious side effects that you need to tell your doctor about immediately. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one side effect at the same time.

These serious side effects include:

- Skin problems
- Lung problems (pneumonitis)
- Gut problems (colitis)
- Liver problems (hepatitis)
- Hormone gland problems - especially thyroid, pituitary, adrenal glands and the pancreas
- Type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes)
- Kidney problems (nephritis and kidney failure)
- Central nervous system problems (such as meningitis)
- Infusion-related reactions
- Muscle problems (inflammation of the muscles called myositis)
- Inflammation of the heart muscle (myocarditis)
- A disease where the immune system makes too many of otherwise normal infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (haemophagocytic lymphohistiocytosis) (see ‘Possible side effects’ for the list of signs and symptoms)
- Problems in other parts of the body (see ‘Possible side effects’).

Look out for these side effects while you are receiving LIBTAYO. See ‘Possible side effects’ section in section 4. If you have any of these effects, talk to your doctor immediately.

Your doctor may give you other medicines in order to stop more severe reactions and reduce your symptoms. Your doctor also may delay your next dose of LIBTAYO or stop your treatment.

Children and adolescents

LIBTAYO should not be used in children and adolescents below 18 years of age.

Other medicines and LIBTAYO

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking or have ever taken any of the following medicines:

- a cancer medicine called idelalisib
- medicines that make your immune system weak - examples include corticosteroids, such as prednisone. These medicines may interfere with the effect of LIBTAYO. However, once you are treated with LIBTAYO, your doctor may give you corticosteroids to reduce the side effects that you may have with LIBTAYO.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

- LIBTAYO can harm your unborn baby.
- Tell your doctor immediately if you become pregnant while you are being treated with LIBTAYO.
- If you are able to become pregnant, you must use an effective method of contraception to avoid becoming pregnant:
 - while you are being treated with LIBTAYO and
 - for at least 4 months after the last dose.
- Talk to your doctor about the contraception methods that you must use during this time.

Breast-feeding

- If you are breast-feeding or plan to breast-feed, ask your doctor for advice before you are given this medicine.

- Do not breast-feed while you are being treated with LIBTAYO and for at least 4 months after the last dose.
- It is not known if LIBTAYO passes into your breast milk.

Driving and using machines

LIBTAYO has no or minor influence on your ability to drive and use machines. If you feel tired, do not drive or use machines until you feel better.

3. How you are given LIBTAYO

- LIBTAYO will be given to you in a hospital or clinic-supervised by a doctor experienced in cancer treatment.
- LIBTAYO is given as a drip into a vein (intravenous infusion).
- The infusion will last about 30 minutes.
- LIBTAYO is usually given every 3 weeks.

How much you will receive

The recommended dose of LIBTAYO is 350 mg.

Your doctor will decide how much LIBTAYO you will receive and how many treatments you will need.

Your doctor will test your blood for certain side effects during your treatment.

If you miss an appointment

Call your doctor as soon as possible to make another appointment. It is very important that you do not miss a dose of this medicine.

If you stop receiving LIBTAYO

Do not stop treatment of LIBTAYO unless you have discussed this with your doctor. This is because stopping your treatment may stop the effect of the medicine.

Patient Alert Card

The information in this Package Leaflet can be found in the Patient Alert Card you have been given by your doctor. It is important that you keep this Patient Alert Card and show it to your partner or caregivers.

If you have any questions about your treatment, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

LIBTAYO acts on your immune system and may cause inflammation in parts of your body (see the conditions listed in ‘Look out for side effects’ in section 2). Inflammation may cause serious damage to your body and may need treatment or require you to stop treatment with LIBTAYO. Some inflammatory conditions may also lead to death.

Seek urgent medical attention if you have any of the following signs or symptoms, or if they get worse:

- **Skin problems** such as rash or itching, skin blistering or ulcers in mouth or other mucous membrane.
- **Lung problems (pneumonitis)** such as new or worsening cough, being short of breath or chest pain.
- **Gut problems (colitis)** such as frequent diarrhoea often with blood or mucus, more bowel movements than usual, stools that are black or tarry, and severe stomach (abdomen) pain or tenderness.
- **Liver problems (hepatitis)** such as yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on right side of your stomach (abdomen), feeling sleepy, dark urine (the colour of tea), bleeding or bruising more easily than normal and feeling less hungry than usual.
- **Hormone gland problems** such as headache that will not go away or unusual headaches, fast heartbeat, increased sweating, feeling more cold or hot than usual, very tired, dizzy or fainting, weight gain or weight loss, feeling more hungry or thirsty than usual, hair loss, constipation, your voice gets deeper, very low blood pressure, passing water more often than usual, nausea or vomiting, stomach (abdomen) pain, changes in mood or behaviour (such as decreased sex drive, being irritable or forgetful).

- **Symptoms of type 1 diabetes or diabetic ketoacidosis** such as feeling more hungry or thirsty than usual, needing to urinate more often, weight loss, feeling tired or feeling sick, stomach pain, fast and deep breathing, confusion, unusual sleepiness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.
- **Kidney problems (nephritis and kidney failure)** such as passing water less often than usual, passing blood, swollen ankles and feeling less hungry than normal.
- **Infusion-related reactions (sometimes can be severe or life-threatening)** such as chills, shaking or fever, itching or rash, flushing or swollen face, being short of breath or wheezing, feeling dizzy or feel like passing out and back or neck pain, nausea, vomiting or abdominal pain.
- **Problems in other parts of the body** such as:
 - **Nervous system problems** such as headache or stiff neck, fever, feeling tired or weak, chills, vomiting, confusion, memory problems or feeling sleepy, fits (seizures), seeing or hearing things that are not really there (hallucinations), severe muscle weakness, tingling, numbness, weakness or burning pain in arms or legs, paralysis in the extremities
 - **Muscle and joint problems** such as joint pain or swelling, muscle pain, weakness or stiffness
 - **Eye problems** such as changes in eyesight, eye pain or redness, sensitivity to light
 - **Heart and circulatory problems** such as changes in heartbeat, heart beating fast, seeming to skip a beat or pounding sensation, chest pain, shortness of breath
 - **Other:** dryness in many parts of the body from mouth to eyes, nose, throat and the top layers of skin, bruises on the skin or bleeding, enlarged liver and/or spleen, lymph node enlargement.

The following side effects have been reported in clinical trials of patients treated with cemiplimab alone:

Very common (may affect more than 1 in 10 people):

- feeling tired
- muscle pain or bone pain
- rash
- diarrhoea (loose stools)
- decreased number of red blood cells
- nausea
- feeling less hungry
- itching
- constipation
- cough
- stomach pain (abdominal pain)
- upper respiratory tract infection.

Common (may affect up to 1 in 10 people):

- vomiting
- shortness of breath
- fever
- urinary tract infection
- headache
- swelling (oedema)
- thyroid gland problems (hyperthyroidism and hypothyroidism)
- high blood pressure
- increased liver enzymes in blood
- patches of thick, scaly, or crusty skin (actinic keratosis)
- cough, inflammation of the lungs
- infusion-related reactions
- inflammation of the liver
- inflammation of the intestines (diarrhoea, more bowel movements than usual, stools that are black or tarry, severe stomach (abdomen) pain or tenderness)
- inflammation of the mouth

- abnormal kidney function test
- inflammation of the nerves causing tingling, numbness, weakness or burning pain of the arms or legs
- inflammation of the kidneys.

Uncommon (may affect up to 1 in 100 people):

- joint pain, swelling, polyarthritis and joint effusion
- bruises on the skin or bleeding
- inflammation of the thyroid
- inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired or chest pain
- decreased secretion of hormones produced by the adrenal glands
- muscle weakness
- inflammation of the pituitary gland situated at the base of the brain
- inflammation of the covering of the heart
- dryness in many parts of the body, from mouth to eyes, nose, throat and the top layers of skin
- inflammation of the muscles which may include muscle pain or weakness (myositis) and could be associated with a rash (dermatomyositis)
- inflammation of the stomach lining
- muscle pain or stiffness (polymyalgia rheumatica).

Rare (may affect up to 1 in 1000 people):

- inflammation of brain and spinal cord membranes, which can be caused by infection
- type 1 diabetes that may include feeling more hungry or thirsty than usual, needing to urinate more often, weight loss, and feeling tired, or diabetic ketoacidosis
- eye pain, irritation, itchiness or redness, inflammation, blurred vision, uncomfortable sensitivity to light (uveitis and keratitis)
- a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities
- a condition in which the muscles become weak and tire easily, muscle pain.

Other side effects that have been reported

(frequency not known):

- organ transplant rejection
- inflammation of the bladder. Signs and symptoms may include frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in the lower abdomen
- haemophagocytic lymphohistiocytosis. A disease in which your immune system makes too many of otherwise normal infection fighting cells called histiocytes and lymphocytes. Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney and heart problems
- coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency).

The following side effects have been reported in clinical trials of patients treated with cemiplimab in combination with chemotherapy:

Very common (may affect more than 1 in 10 people):

- decreased number of red blood cells
- hair loss
- muscle pain or bone pain
- nausea
- feeling tired
- inflammation of the nerves causing tingling, numbness, weakness or burning pain of the arms or legs
- high blood sugar
- feeling less hungry
- increased liver enzymes in blood
- decrease in the number of white blood cell (neutrophils)
- constipation
- decrease in the number of platelets
- shortness of breath
- rash

- vomiting
- weight loss
- trouble sleeping
- diarrhoea (loose stools)
- low levels in the blood of a protein called ‘albumin’.

Common (may affect up to 1 in 10 people):

- abnormal kidney function test
- thyroid gland problems (hyperthyroidism and hypothyroidism)
- cough, inflammation of the lungs
- itching
- inflammation of the kidneys
- inflammation of the intestines (diarrhoea, more bowel movements than usual, stools that are black or tarry, severe stomach (abdomen) pain or tenderness)
- joint pain, swelling, polyarthritis and joint effusion.

Uncommon (may affect up to 1 in 100 people):

- inflammation of the thyroid
- infusion-related reactions
- type 1 diabetes that may include feeling more hungry or thirsty than usual, needing to urinate more often, weight loss, and feeling tired.

Other side effects that have been reported

(frequency not known):

- coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)
- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency).

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LIBTAYO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Store in the original container in order to protect from light.

From a microbiological point of view the prepared solution for infusion should be used immediately. If diluted solution is not administered immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Chemical and physical in-use stability has been demonstrated as follows:

- at room temperature up to 25°C for no more than 8 hours from the time of infusion preparation to the end of infusion.
Or
- under refrigeration at 2°C to 8°C for no more than 10 days from the time of infusion preparation to the end of infusion. Allow the diluted solution to come to room temperature prior to administration.

Do not store any unused portion of the infusion solution for re-use. Any unused portion of the infusion solution should not be re-used and should be disposed in accordance with local requirements.

6. Contents of the pack and other information

What LIBTAYO contains

The active substance is cemiplimab:

- One ml of concentrate contains 50 mg of cemiplimab.
- Each vial contains 350 mg cemiplimab in 7 ml of concentrate.

The other ingredients are L-Histidine, L-Histidine monohydrochloride monohydrate, L-proline, sucrose, polysorbate 80 and water for injections.

What LIBTAYO looks like and contents of the pack

LIBTAYO concentrate for solution for infusion (sterile concentrate) is supplied as a clear to slightly opalescent, colourless to pale yellow sterile solution that may contain trace amounts of translucent to white particles.

Each carton contains 1 glass vial with 7 ml of concentrate.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor.

This leaflet was last revised in June 2024

Information for healthcare professionals

The following information is intended for healthcare professionals only:

Instructions for use

Preparation

- Visually inspect the medicinal product for particulate matter and discoloration prior to administration. LIBTAYO is a clear to slightly opalescent, colourless to pale yellow solution that may contain trace amounts of translucent to white particles.

- Discard the vial if the solution is cloudy, discoloured or contains extraneous particulate matter other than trace amounts of translucent to white particles.

- Do not shake the vial.

- Withdraw 7 ml (350 mg) from the vial of LIBTAYO and transfer into an intravenous infusion bag containing sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection. Mix the diluted solution by gentle inversion. Do not shake the solution. The final concentration of the diluted solution should be between 1 mg/ml to 20 mg/ml.

- LIBTAYO is for single use only. Dispose of any unused medicinal product or waste material in accordance with local requirements.

Storage of diluted solution

LIBTAYO does not contain a preservative.

From a microbiological point of view the prepared solution for infusion should be used immediately. If diluted solution is not administered immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Chemical and physical in-use stability has been demonstrated as follows:

- at room temperature up to 25°C for no more than 8 hours from the time of infusion preparation to the end of infusion.
Or
- under refrigeration at 2°C to 8°C for no more than 10 days from the time of infusion preparation to the end of infusion. Allow the diluted solution to come to room temperature prior to administration.

Do not freeze.

Administration

- LIBTAYO is for intravenous use. It is administered by intravenous infusion over 30 minutes through an intravenous line containing a sterile, non-pyrogenic, low-protein binding, in-line or add-on filter (0.2 micron to 5 micron pore size).

- Do not co-administer other medicines through the same infusion line.