

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE LIBTAYO

#### Cemiplimab for injection

Read this carefully before you start taking **LIBTAYO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LIBTAYO**.

#### What is LIBTAYO used for?

LIBTAYO is a prescription medicine used to treat:

##### Cutaneous Squamous Cell Carcinoma

- adult patients with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) when your cancer:
  - has spread or grown, and
  - your tumour cannot be removed by surgery or treated with radiation.

##### Non-Small Cell Lung Cancer

- adult patients with a type of lung cancer called non-small cell lung cancer (NSCLC) and your cancer:
  - has spread, or grown and you are not a candidate to undergo surgery or be treated with chemotherapy and radiation
  - your tumour was tested, and found to express a specific protein called programmed death-ligand 1 (PD-L1) in 50% or more of the tumour cells, and
  - your tumour does not have an abnormal epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or c-ROS oncogene 1 (ROS1) gene.

##### Basal Cell Carcinoma

- patients with a type of skin cancer called basal cell carcinoma (BCC) when your cancer:
  - has been previously treated with a drug called a hedgehog pathway inhibitor.

##### Cervical Cancer

- adult patients with cervical cancer when the cancer has worsened on or after chemotherapy.

For the following indication, LIBTAYO has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more

information, talk to your healthcare professional.

- for the treatment of adult patients with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) when your cancer:
  - has spread or grown, and
  - your tumour cannot be removed by surgery or treated with radiation.

For the following indications, LIBTAYO has been approved without conditions. This means it has passed Health Canada's review and can be bought and sold in Canada.

- for the treatment of adult patients with a type of lung cancer called non-small cell lung cancer (NSCLC) and your cancer:
  - has spread, or grown and you are not a candidate to undergo surgery or be treated with chemotherapy and radiation
  - your tumour was tested, and found to express a specific protein called programmed death-ligand 1 (PD-L1) in 50% or more of the tumour cells, and
  - your tumour does not have an abnormal epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or c-ROS oncogene 1 (ROS1) gene.
- for the treatment of patients with a type of skin cancer called basal cell carcinoma (BCC) when your cancer:
  - has been previously treated with a drug called a hedgehog pathway inhibitor.
- for the treatment of adult patients with cervical cancer when the cancer has worsened on or after chemotherapy.

### ***What is a Notice of Compliance with Conditions (NOC/c)?***

*A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.*

*Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.*

*Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.*

### **How does LIBTAYO work?**

LIBTAYO works by helping your immune system fight your cancer.

### **What are the ingredients in LIBTAYO?**

Medicinal ingredients: Cemiplimab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, L-proline, Polysorbate 80, Sucrose, Water for injection

**LIBTAYO comes in the following dosage forms:**

LIBTAYO comes in a 10mL glass vial containing either 250 mg or 350 mg of cemiplimab.

**Do not use LIBTAYO if:**

- You are allergic to cemiplimab or any of the other ingredients in this medicine. Talk to your health care professional if you are not sure.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LIBTAYO. Talk about any health conditions or problems you may have, including if you have:**

- An autoimmune disease (a condition where your body attacks its own cells)
- Had an organ transplant
- Lung or breathing problems
- Liver problems
- Kidney problems
- Diabetes
- Any other medical conditions
- A history of taking idelalisib (a medication to treat cancer)

**Other warnings you should know about:****Pregnancy:**

- If you are pregnant, or are planning to have a baby, tell your healthcare professional before taking this medicine. You must not use LIBTAYO if you are pregnant unless your healthcare professional specifically recommends it.
- LIBTAYO can cause harm to your unborn baby.
- If you are a woman who could become pregnant, you must use effective birth control while you are being treated with LIBTAYO and for at least 4 months after your last dose.

**Breast-feeding:**

- If you are breast-feeding, or plan to breast-feed, tell your healthcare professional
- Do not breast-feed while receiving LIBTAYO and for at least 4 months after your last dose
- It is unknown if LIBTAYO passes into your breast milk. A risk to the breast-fed infant cannot be excluded

**Children and adolescents:**

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

**Driving and using machines**

- It is not known whether LIBTAYO affects your ability to drive or use tools or machines. However, if you feel tired, do not drive or use tools or machines until you feel better.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with LIBTAYO:**

- There are no known drug-drug interaction with LIBTAYO.

**How to take LIBTAYO:**

- You will receive LIBTAYO in a hospital or clinic under the supervision of an experienced healthcare professional
- You will receive LIBTAYO as a drip into a vein (intravenous infusion)
- It will last about 30 minutes
- LIBTAYO is usually given every 3 weeks. Your doctor may choose to treat you with an every 2 week regimen if more appropriate for you.

**Usual dose:**

The recommended dose of LIBTAYO is 350 mg every 3 weeks. 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.

**Overdose:**

If you think you have taken too much LIBTAYO, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss any appointments, call your healthcare professional as soon as possible to reschedule your appointment. It is very important that you do not miss a dose of this medicine.

**What are possible side effects from using LIBTAYO?**

These are not all the possible side effects that you may feel when taking LIBTAYO. If you experience any side effects not listed here, contact your healthcare professional.

These may happen anytime during treatment or even after your treatment has ended. You may have more than one side effect at the same time.

The following side effects have been reported in clinical trials:

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

- Abdominal pain
- Constipation
- Cough
- Decreased appetite
- Diarrhea
- Feeling tired
- Itching (pruritis)
- Low red blood cell count (anemia)
- Muscle and bone pain
- Nausea
- Rash
- Upper respiratory tract infection

Common (may affect less than 1 in 10, but more than 1 in 100 people)

- Abdominal swelling
- Abnormal kidney function test
- Changes in blood, liver, and urine laboratory values
- Changes in weight
- Chills
- Difficulty breathing
- Difficulty sleeping (insomnia)
- Dizziness
- Dry mouth
- Dry skin
- Eczema
- Fever
- Flu-like symptoms
- Gastric reflux
- Headache
- High blood pressure (hypertension)
- Infusion-related reactions
- Mouth sores
- Muscle spasms
- Numbness, tingling or pain in your feet or hands (peripheral neuropathy)
- Scaly patches on the skin (actinic keratosis)
- Swelling (oedema)
- Urinary tract infection
- Vomiting

Uncommon (may affect less than 1 in 100, but more than 1 in 1000 people)

- Chest pain, shortness of breath, fatigue, abdominal or leg swelling (pericarditis)
- Eye redness or pain, blurred vision (keratitis)
- Type 1 diabetes

<b>Serious side effects and what to do about them</b>		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
<b>Very Common</b>		
Itching		√
Rash		√
Respiratory tract (lung) infection: runny nose, shortness of breath, fever		√
<b>Common</b>		
Arthritis: pain or swelling in the joints		√
Colitis (inflammation of the colon): diarrhea, stools that are black, tarry, sticky, or have blood or mucous, severe abdominal pain		√
Dyspnea (shortness of breath)		√
Hepatitis (inflammation of the liver): yellowing of the skin or the whites of the eyes, severe nausea or vomiting, pain on the right side of the abdomen, feeling sleepy, dark urine, bleeding or bruising more easily than normal, decreased appetite		√
Hyperthyroidism (overactive thyroid gland): rapid or irregular heartbeat, high blood pressure, increased sweating, feeling more hot than usual, mood swings		√
Hypothyroidism (underactive thyroid gland): feeling tired, weight gain, constipation, feeling more cold than usual, hair loss, depression		√
Infusion-related reactions: chills or shaking, fever, itching or rash, flushing or swollen face, shortness of breath or wheezing, dizziness, back or neck pain		√
Muscle weakness	√	
Nephritis (inflammation of the kidneys): swelling of the ankles, decreased urination, decreased appetite		√
Peripheral neuropathy (damaged nerves): numbness, tingling or pain in your hands or feet		√
Pneumonia (infection in the lungs): new or worsening cough, fever, shortness of breath		√
Pneumonitis (inflammation of the lungs): new or worsening cough, shortness of breath, chest pain		√
Stomatitis (inflammation of the mouth): painful mouth ulcers, blisters, or peeling	√	
Urinary tract infection: pain or burning with urination, increased urination		√

<b>Serious side effects and what to do about them</b>		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
<b>Uncommon</b>		
Adrenal insufficiency (underactive adrenal gland): feeling tired, dizzy or weak, nausea, vomiting, diarrhea, low blood pressure		√
Hypophysitis (inflammation of the pituitary gland): headache, nausea, vomiting, increased thirst, vision changes		√
Myocarditis (inflammation of heart muscles): chest pain, rapid or irregular heartbeat, shortness of breath		√
Myositis (inflammation of the muscles): muscle pain or weakness, which could be associated with a rash (dermatomyositis), feeling tired after standing or walking		√
Pericarditis (inflammation of heart membrane): chest pain, shortness of breath, feeling tired, swelling of the abdomen or legs		√
Skin blistering		√
Sjogren's syndrome (disease affecting salivary and tear glands): dry eyes, nose, mouth, and throat		√
Thyroiditis (inflammation of the thyroid gland): irritability, rapid heartbeat, changes in weight, feeling tired, constipation, depression		√
Type 1 diabetes (blood sugar problems): hunger or thirst, increased urination, weight loss		√
Ulcers in mouth or other mucous membranes		√
<b>Rare</b>		
Chronic inflammatory demyelinating polyradiculoneuropathy: tingling or loss of feeling in your arms and legs, weakness		√
Encephalitis (inflammation of the brain): headache, fever, pain in muscles or joints, feeling tired or weak		√
Meningitis (inflammation of the protective covering of the brain): headache, nausea, vomiting, decreased appetite, confusion, fever, seizures		√
Myasthenia gravis: feeling tired or weak, double vision, difficulty speaking, swallowing or chewing		√
Paraneoplastic encephalomyelitis: loss of muscle tone or coordination, muscle weakness		√

Serious side effects and what to do about them		
Symptom / effect	Talk to your healthcare professional	
	Only if severe	In all cases
Polymyalgia rheumatica: pain in the shoulders, neck, upper arms, buttocks or hips, stiffness, feeling tired		√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

LIBTAYO should not be used after the expiry date which is stated on the label and carton.

LIBTAYO should be stored in a refrigerator (2°C to 8°) in its original package to protect from light.

Do not freeze.

Do not shake.

From time of preparation by diluting in an intravenous (IV infusion) bag, LIBTAYO can be stored before use for no more than 8 hours at temperatures up to 25°C, and no more than 24 hours in a refrigerator (2°C to 8°C). If refrigerated, the vials and/or intravenous bags must be allowed to reach room temperature prior to use.

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.

Keep out of reach and sight of children.

#### If you want more information about LIBTAYO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the sanofi-aventis Canada website [www.sanofi.ca](http://www.sanofi.ca), or

by calling 1-800-265-7927.

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