

Medication Information Sheet

cemiplimab (SEM ip LI mab)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Libtayo™

Appearance: clear to slightly opalescent, colourless to pale yellow solution mixed into larger bags of fluids

What is this medication for?

- For treating a type of skin cancer called Squamous Cell Carcinoma

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- an organ transplant,
- immune conditions,
- diabetes,
- problems with your hormone producing glands (such as thyroid, pituitary, adrenal glands and pancreas),
- kidney, liver, lung problems, or
- any allergies

Talk to your health care team if you have previously been given a medication called idelalisib for another type of cancer. You may be more likely to experience certain side effects with cemiplimab.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time for at least **4 months** after your last dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and for at least **4 months** after your last dose.

How is this medication given?

- This drug is given through an IV (injected into a vein). Talk to your health care team about your treatment schedule.
- If you missed your treatment appointment, talk to your health care team to find out what to do.

What else do I need to know while on this medication?

Will this medication interact with other medications or natural health products?

- Although this medication is unlikely to interact with other medications, vitamins, foods and natural health products, tell your health care team about all of your:
 - ◊ prescription and over-the-counter (non-prescription) medications and all other drugs, such as marijuana (medical or recreational)
 - ◊ natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.

What should I do if I feel unwell, have pain, a headache or a fever?

- **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time
- OR
- 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- Ask your health care team for the [Fever](#) pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- **Talk to your health care team before you start taking** Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO consider asking someone to drive you to and from the hospital on your treatment days. You may feel drowsy or tired after your treatment.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.

What are the side effects of this medication?

The following table lists side effects that you may have when getting cemiplimab. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on cemiplimab.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loose watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it or told you to take it. • Do not eat foods or drinks with artificial sweetener (like chewing gum or “diet” drinks), coffee and alcohol. 	<p>Talk to your health care team for advice.</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. • Talk to your health care team if you can't drink 6-8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p> <p>In rare cases, your diarrhea may be severe due to inflammation of the intestines if:</p> <ul style="list-style-type: none"> • You have blood in your stool (poo) or • You have more than 4 bowel movements (going poo) a day (if that is not normal for you) <p>If this happens, talk to your health care team or go to the emergency room right away.</p>	<p>Talk to your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. 	<p>Talk to your health care team if it does not improve or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Ask family or friends to help you with things like housework, shopping, and child or pet care. • Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	
<p>Nausea and vomiting (generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (like coffee, tea) and avoid alcohol. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea and Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe. 	<p>Talk to your health care team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Constipation</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Having bowel movements (going poo) less often than normal. • Small hard stools (poo) that look like pellets. • The need to push hard and strain to have any stool (poo) come out. • Stomach ache or cramps. • A bloated belly, feeling of fullness, or discomfort. • Leaking of watery stools (poo). • Lots of gas or burping. • Nausea or vomiting <p>What to do?</p> <p>To help prevent constipation:</p> <ul style="list-style-type: none"> • Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. • Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. • Be Active. Exercise can help to keep you regular. • If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation:</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. <p>Ask your health care team for the Constipation Pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p>Rash (may be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Your skin may look red or feel warm, like a sunburn. • Your skin may have bumps, itch, burn, sting or feel very tender when touched. 	<p>Talk to your health care team for advice.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <p>To prevent and treat dry skin:</p> <ul style="list-style-type: none"> • Use fragrance-free skin moisturizer. • Protect your skin from the sun and the cold. • Use sunscreen with UVA and UVB protection and a SPF of at least 30. • Avoid perfumed products and lotions that contain alcohol. • Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. <p>In rare cases, rash may be severe if:</p> <ul style="list-style-type: none"> • The rash covers more than a third of your skin (for example your whole trunk, or an arm AND a leg) or • The rash causes your skin to blister or peel. <p>If this happens, talk to your health care team or go to the emergency room right away.</p>	<p>Talk to your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>
<p>Cough and feeling short of breath</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: <ul style="list-style-type: none"> ◦ Wheezing or a whistling breathing ◦ Runny nose ◦ Sore throat ◦ Heartburn ◦ Weight loss ◦ Fever and chills • Rarely this may be severe with chest pain, trouble breathing or coughing up blood. <p>What to do?</p> <ul style="list-style-type: none"> • Check your temperature to see if you have a fever. Read the above section “What should I do if I feel unwell, have pain, a headache or a fever?”. 	<p>Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST get emergency medical help right away.</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. • If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
<p>Low Appetite</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • Try to eat your favourite foods • Eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have no appetite <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe
<p>Headache</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Mild headache <p>What to do?</p> <ul style="list-style-type: none"> • Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. • Read the above section: “What should I do if I feel unwell, have pain, a headache or a fever?” before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. • Rest often and try light exercise (such as walking) as it may help. <p>Ask your health care team for the Pain pamphlet for more information.</p>	Talk to your health care team if it does not improve or if it is severe

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- feel more tired and weaker than normal, have pale skin
- dark or blood in urine, yellowish skin or eyes, pain on the right side of your belly
- unusual changes in your weight
- unusual darkening of skin, rash that look like small bruises, purplish-red spots or patches on your skin
- trouble sleeping, feeling irritable or overactive
- signs of an allergic reaction such as rash, swollen lips, face or tongue, chest and throat tightness during and shortly after the drug is given
- fever (oral temperature of 38.3°C (100.9°F) or higher at any time OR 38.0°C (or 100.4°F) or higher for at least one hour)
- muscle or joint weakness, pain or difficulty moving your arms, legs or upper body
- trouble with facial movements, including speaking, chewing or swallowing
- severe dry mouth or eyes that persist
- peeing more than normal and feeling very thirsty
- sores in the throat or mouth that makes it difficult to drink or eat
- swelling in your legs or ankles, passing very little or no pee
- unusual bleeding or bruising (such as bleeding from your gums, unusual or heavy nosebleeds, or pink coloured pee. If you have bleeding that is severe or doesn't stop, you must get emergency help.
- sudden fever with severe headache and stiff neck, confusion
- fainting, irregular or fast heartbeat
- trouble breathing, shortness of breath, pain in your chest

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact: _____

Evenings, weekends and holidays: _____

Other Notes:
