

For the Patient: **SMAVCEM**

Other Names: Treatment of Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma Using Cemiplimab

SM = Skin and Melanoma

AV = Advanced

CEM = Cemiplimab

ABOUT THIS MEDICATION

What is this drug used for?

- Cemiplimab (sem' ip li" mab) is a drug that is used to treat a type of skin cancer called cutaneous squamous cell carcinoma (CSCC), that has spread to other parts of the body or cannot be removed by surgery or radiation.

How does this drug work?

- Cemiplimab is a type of therapy called immunotherapy. It is an antibody designed to help your own body's immune system target cancer cells to stop them from growing.

INTENDED BENEFITS

- Cemiplimab is being given to destroy and/or limit the growth of squamous cells. It may improve your current symptoms, and delay or prevent the onset of new ones.

TREATMENT SUMMARY

How is this drug given?

- Cemiplimab will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 30 minutes.
- You will be treated with cemiplimab once every 3 weeks. This 3 weeks period is called a "cycle". The cycle is repeated as long as you are benefiting from treatment and not having too many side effects.

What will happen while I am being treated?

- A blood test (lab work) and other tests are done before starting each treatment cycle at the time you see your oncologist.
- The treatment may be interrupted based on your test results and/or side effects.

INSTRUCTIONS FOR THE PATIENT

What other drugs or foods can interact with cemiplimab?

- Other drugs may interact with cemiplimab. Check with your doctor or pharmacist before you start or stop taking any other drugs including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of cemiplimab.

Other important things to know:

- **Before you are given cemiplimab**, talk to your doctor or pharmacist if you:
 - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, lupus, rheumatoid arthritis or sarcoidosis.
 - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone or dexamethasone.
 - had an organ transplant, such as a kidney transplant.
 - have any other medical conditions.
- It is very important to tell your doctor immediately if you have, or develop, any of the symptoms listed under **Serious Side Effects. Do not try to treat or diagnose symptoms yourself.**
- You may have a **transient worsening of disease** before the tumour shrinks. Tumour response will be assessed during treatment.
- Cemiplimab may damage sperm and may harm the baby if used during pregnancy. You must use **birth control** while being treated with cemiplimab and for at least 4 months after your last dose. Tell your doctor right away if you or your partner becomes pregnant.
- Cemiplimab may pass into your breast milk. **Do not breastfeed** during treatment
- **Tell** doctors or dentists that you are being treated with cemiplimab before you receive any treatment from them.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Cemiplimab may cause serious immune reactions against your own body (autoimmune) affecting many parts.

Are there any risks?

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Cemiplimab can cause serious side effects in many parts of your body. These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment with cemiplimab.
- **Tell** your doctor as soon as possible if you have any of serious side effects listed in the table below or your symptoms get worse.
- **Do not try to treat or diagnose symptoms yourself.** Getting medical treatment right away may keep the problem from becoming more serious.

The following side effects were most frequently reported:

Very common (more than 1 in 10 people)

- Feeling tired
- Rash
- Itching
- Diarrhea (loose stools)

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation of the intestines (colitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself. • blood or mucus in stools or dark, tarry, sticky stools • severe stomach pain (abdominal pain) or tenderness 	<p>Very Common (more than 1 in 10)</p>
<p>Skin problems <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rash • dry skin 	<p>Very Common (more than 1 in 10)</p>
<p>Inflammation of the thyroid gland (hyperthyroidism, hypothyroidism) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rapid heart beat • weight loss or gain • increased sweating • hair loss • feeling cold • constipation or diarrhea • your voice gets deeper • muscle aches • changes in sleep patterns 	<p>Common (less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of the lungs (pneumonitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • shortness of breath • chest pain • coughing 	<p>Common (less than 1 in 10 but more than 1 in 100)</p>
<p>Problems with muscles <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • back pain • spasms • weakness • muscle pain 	<p>Common (less than 1 in 10 but more than 1 in 100)</p>

SERIOUS SIDE EFFECTS	How common is it?
<p>Inflammation of the liver (hepatitis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • nausea or vomiting • loss of appetite • pain on the right side of your stomach • yellowing of your skin or the whites of your eyes • dark urine • bleeding or bruise more easily than normal 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<p>Infusion reactions <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • shortness of breath • itching or rash • dizziness • fever • wheezing • flushing • feeling like passing out 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<p>Problems in other organs (nervous system, eyes) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • tingling, numbness, lack of energy • changes in eyesight • dizziness 	<p>Uncommon</p> <p>(less than 1 in 100 but more than 1 in 1000)</p>
<p>Inflammation of the kidneys (nephritis) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • changes in the amount or colour of your urine 	<p>Uncommon</p> <p>(less than 1 in 100 but more than 1 in 1000)</p>
<p>Problems in the pancreas <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • abdominal pain • nausea and vomiting 	<p>Uncommon</p> <p>(less than 1 in 100 but more than 1 in 1000)</p>

SERIOUS SIDE EFFECTS	How common is it?
Blood sugar problems (type 1 diabetes mellitus) <i>Symptoms may include:</i> <ul style="list-style-type: none"> • hunger or thirst • a need to urinate more often • weight loss 	Uncommon (less than 1 in 100 but more than 1 in 1000)

OTHER SIDE EFFECTS	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Allergic reactions may rarely occur. Signs of an allergic reaction may include dizziness, fever, chills, rash, itching, back or neck pain, flushing, face swelling or breathing problems. This can occur immediately or several hours after receiving cemiplimab.	Tell your nurse if this happens while you are receiving cemiplimab or contact your oncologist immediately if this happens after you leave the clinic.
Diarrhea may sometimes occur.	Contact your oncologist immediately or get emergency help.
Nausea and vomiting may occur. Most people have little or no nausea.	See or call your doctor as soon as possible.
Skin rashes and/or itching may sometimes occur.	
Constipation may sometimes occur.	
Muscle pain or joint pain may sometimes occur.	
Tiredness and lack of energy may sometimes occur.	
Loss of appetite may sometimes occur.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*

OTHER SIDE EFFECTS	MANAGEMENT
Hair loss does not occur with cemiplimab.	

***Please ask your oncologist, nurse or pharmacist for a copy.**

If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:

_____ at telephone number: _____



Provincial Health Services Authority

MEDICAL ALERT

NAME _____

has received

CHECKPOINT INHIBITOR IMMUNOTHERAPY:

Immune-Mediated Adverse Reactions

ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS

SEVERE IMMUNE-MEDIATED ADVERSE REACTIONS
Including enterocolitis, intestinal perforation, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, endocrinopathy, pneumonitis, myositis, myocarditis and toxicities in other organ systems. Duration of risk after treatment is unknown.

FOR MORE INFORMATION:

- BC Cancer - Abbotsford604-851-4710
- BC Cancer - Kelowna250-712-3900
- BC Cancer - Prince George.....250-645-7300
- BC Cancer - Surrey604-930-4055
- BC Cancer - Vancouver.....604-877-6000
- BC Cancer - Victoria.....250-519-5500

www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual

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To Whom It May Concern:

RE: _____

Medical Oncologist _____

Immunotherapy Regimen _____

This patient is receiving **immunotherapy** at the BC Cancer and is at risk of **immune-related toxicities** which may be life threatening and require urgent management.

Immunotherapy toxicities are different from those encountered with standard chemotherapy or targeted therapies. The immune system may become dysregulated during immunotherapy treatment, leading to symptoms and findings which mimic autoimmune disorders. Adverse events can occur during or following treatment and can be life threatening. Any organ system in the body is at risk including, but not limited to:

- Lungs (pneumonitis, pleuritis, sarcoidosis)
- Gastrointestinal (colitis, ileitis, pancreatitis)
- Liver (hepatitis)
- Skin (rash, Stevens-Johnson syndrome)
- Endocrine (hypophysitis, adrenal insufficiency, hypo/hyperthyroidism, type 1 diabetes mellitus)
- Renal (interstitial nephritis)
- Blood (hemolytic anemia, thrombocytopenia, neutropenia)
- Neurologic (encephalitis, Guillain-Barré syndrome, meningitis, myasthenia gravis, neuropathy)
- Musculoskeletal (myositis, arthritis)
- Cardiovascular (pericarditis, myocarditis, vasculitis)
- Ophthalmologic (uveitis, scleritis, episcleritis, conjunctivitis, retinitis)

Management of immune-related toxicities necessitates prompt coordination with a medical oncologist with **initiation of high dose corticosteroids**, and may require referral to the appropriate subspecialty. If you suspect your patient is presenting with immune-related toxicity, **please contact the patient's medical oncologist** directly or if after hours contact the on-call physician, or as per your local centre's process (next page). Additional information on immunotherapy toxicity treatment algorithms is located at the end of the above posted protocol at www.bccancer.bc.ca.

BC CANCER CENTRES	CONTACT INFORMATION AND PROCESS
Abbotsford	Contact the patient’s medical oncologist immediately by calling the Abbotsford Regional Hospital and Cancer Centre (ARHCC) switchboard at (604) 851-4700 and ask for the on-call medical oncologist (24-hour call system).
Kelowna	Between 8:30 am – 5:00 pm, call (250) 712-3900 (press “8” to speak to the Kelowna Centre receptionist) and have an oncologist paged. Outside these hours, call the Kelowna General Hospital switchboard at (250) 862-4000 and ask for the on-call medical oncologist.
Prince George	Between 8:30 am – 4:00 pm Monday to Friday, call (250) 645-7313. Outside these hours, go to the emergency department at the University Hospital of Northern British Columbia (UHNBC).
Surrey	Between 8:30 am – 4:00 pm Monday to Friday (except Statutory holidays), call the Nursing Phone Line at (604) 930-4053. Outside these hours, call the Surrey Memorial Hospital switchboard at (604) 581-2211 and ask for the Fraser Valley on-call medical oncologist.
Vancouver	Between 8:30 am – 4:30 pm Monday to Friday, call the Patient Nurse Line at (604) 877-6025. Outside these hours, call the inpatient unit at (604) 877-6000 and press 1, and ask for the on-call medical oncologist.
Victoria	Between 8:30 am – 4:30 pm Monday-Friday (except Statutory holidays), call (250) 519-5500, and press 1 then 4 to speak with a registered nurse. Outside these hours, call the Royal Jubilee Hospital switchboard at (250) 370-8000 and ask for the on-call medical oncologist.