

For the Patient: HNAVFPMB

Other Names: Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck Using Platinum, Fluorouracil and Pembrolizumab

HN = Head and Neck (Tumour group)

AV = Advanced

P = Platinum (Cisplatin or Carboplatin)

FU = Fluorouracil

PMB=Pembrolizumab

ABOUT THIS MEDICATION

What are these drugs used for?

HNAVFPMB is an intravenous (through the vein) drug treatment for advanced non-small cell cancer with squamous cell type.

This treatment is offered to people who have a good performance status. Performance status is a measure of how well a person is able to perform their usual daily activities.

How do these drugs work?

There are three drugs in this treatment:

Cisplatin or carboplatin, and fluorouracil interfere with the genetic material (DNA) of cancer cells and prevent them from growing.

Pembrolizumab 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

This treatment is being given to destroy and/or to slow down the growth of cancer cells in your body. This treatment can help with controlling some of the symptoms the cancer may be causing and may delay or prevent new symptoms from starting.

TREATMENT SUMMARY

Before your treatment begins:

- You will need to take medications to prevent nausea and vomiting. A common example is ondansetron. Your oncologist will select the most suitable choice(s) for you. You may get it from your regular pharmacy with a doctor's prescription.

How are these drugs given?

- Your treatment plan consists of 4-6 cycles. Each cycle lasts 3 weeks (21 days).
- For each cycle, you will have the three drugs given to you intravenously on Day 1.
 - Pembrolizumab is given first. The infusion lasts about 30 minutes.
 - Cisplatin (or carboplatin) is given next. The infusion lasts about 30 minutes.
 - Fluorouracil is given last.
- You will receive **fluorouracil** at the clinic by the chemotherapy nurse on **day 1 and day 3** of your treatment. The fluorouracil is given using TWO disposable infusion devices called an INFUSOR® or “baby bottle”. Each infusion device delivers the fluorouracil slowly and continuously to your body **over 48 hours or 2 days**. Please see a copy of “*Your INFUSOR® - A Guide for Patients*”, available through your chemotherapy nurse. This is repeated every 3 weeks.
- The chemotherapy nurse will connect the infusion device to your IV site at the clinic, and then you can go about your normal pattern of living, while your **FIRST** fluorouracil infusor device delivers treatment over the 48 hours or 2 days. You will return to clinic on day 3. The **SECOND** infusion device will be connected to your IV site by the chemotherapy nurse. You can go home while your fluorouracil treatment is delivered over the next 48 hours. Total time period of IV fluorouracil infusion is 96 hours or 4 days. You may return to the clinic after 4 days for the nurse to disconnect the infusion device, or you will be instructed how to disconnect yourself at home. Some people may be instructed to go to their local hospital to be disconnected, or may have a home care nurse provide this service, if available.

[HNAVFPMB Treatment Protocol](#)

Cycle 1: Start Date: _____

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pembrolizumab Cisplatin or Carboplatin Fluorouracil	Fluorouracil	Fluorouracil	Fluorouracil	no chemo	no chemo	no chemo
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
no chemo	no chemo	no chemo	no chemo	no chemo	no chemo	no chemo
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
no chemo	no chemo	no chemo	no chemo	no chemo	no chemo	no chemo

This 21-day cycle will occur for a total of 4-6 times.

What will happen when I get my drugs?

- A blood test is done within one month of starting treatment.
- A blood test is done before each treatment cycle. You will be given lab requisitions for these tests to be done on a specific date.
- The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects.
- You will be given a prescription for anti-nausea medications (to be filled at your regular pharmacy) that you need to bring to each of your chemotherapy treatments. Your nurse will tell you when to take the anti-nausea medication during your chemotherapy time, and provide a schedule of when to take it while at home. It is easier to prevent nausea than to treat it once it has occurred, so follow the suggestions given to you.

OTHER INSTRUCTIONS

It is very important to report side effects immediately to your doctor. Do not manage side effects at home without first speaking with your doctor. Be aware that symptoms may be delayed and can develop months after your last dose.

What other drugs or foods can interact with [HNAVFPMB](#)?

- Other drugs may interact with this treatment. 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. Other drugs such as phenytoin (DILANTIN®), warfarin (COUMADIN®) or some drugs that affect the kidneys may interact with HNAVFPMB.
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- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.

Other important things to know:

- **Before you are given pembrolizumab**, 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.
- This treatment may cause sterility in men and menopause in women. If you plan to have children, discuss this with your oncologist before starting treatment.
- This treatment may damage sperm and may cause harm to the baby if used during pregnancy. It is best to use birth control while you are undergoing treatment and for **4 months** after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.

- Tell all doctors including dentists you see that you are being treated with pembrolizumab, cisplatin or carboplatin, and fluorouracil before you receive treatment of any form.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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?

- **Pembrolizumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.**
- The following side effects were most frequently reported:
 - diarrhea
 - itching, rash
 - joint pain
 - feeling tired
 - feeling less hungry
 - cough
- These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment with pembrolizumab.
- **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.

Serious Side Effects Associated with Pembrolizumab

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>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</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</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<p>Inflammation of the pituitary gland (hypophysitis, hypopituitarism, including secondary adrenal insufficiency) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • weight loss • increased sweating, hot flashes • hair loss (includes facial and pubic) • feeling cold • headaches that will not go away or unusual headache • decreased sex drive • vision problems • excessive thirst and urination 	<p>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>

SERIOUS SIDE EFFECTS	How common is it?
<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>
<p>Skin problems <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rash • dry skin 	<p>Common (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>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>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>Rare</p> <p>(less than 1 in 1000 but more than 1 in 10000)</p>
<p>Blood sugar problems (type 1 diabetes mellitus) <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • hunger or thirst • a need to urinate more often • weight loss 	<p>Rare</p> <p>(less than 1 in 1000 but more than 1 in 10000)</p>

SERIOUS SIDE EFFECTS	How common is it?
<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>Rare (less than 1 in 1000 but more than 1 in 10000)</p>

CHEMOTHERAPY SIDE EFFECTS AND MANAGEMENT

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 drugs in your treatment plan.

SERIOUS SIDE EFFECTS	HOW COMMON IS IT?	MANAGEMENT
Cisplatin, carboplatin, and fluorouracil burns if it leaks under the skin.	rare	Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given.
Nausea and vomiting may occur after your treatment and may last for up to 24 hours. Nausea may last longer for some patients.	very common	You will be given a prescription for anti-nausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. Drink plenty of liquids. Eat and drink often in small amounts. Try the ideas in <i>Food Choices to Help Control Nausea</i> .*
Your white blood cells may decrease 7-14 days after your treatment. They usually return to normal before your next treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	common	To help prevent infection: <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your doctor immediately at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough or burning when you pass urine.

SERIOUS SIDE EFFECTS	HOW COMMON IS IT?	MANAGEMENT
<p>Your platelets may decrease 7-14 days after your treatment. They usually return to normal before your next treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.</p>	<p>common</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • Try not to bruise, cut, or burn yourself. • Clean your nose by blowing gently. Do not pick your nose. • Avoid constipation. • Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. <p>Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</p> <ul style="list-style-type: none"> • Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). <p>For minor pain, try acetaminophen (e.g., TYLENOL®) first, to a maximum of 4 g (4000 mg) per day, but occasional use of ibuprofen may be acceptable.</p>
<p>Signs of heart problems such as chest pain or fast or uneven heartbeat.</p>	<p>rare</p>	<p>Contact your oncologist immediately if this happens to you.</p>
<p>Diarrhea may commonly occur.</p>	<p>common</p>	<p>If diarrhea is a problem:</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. <p>Avoid high fibre foods as outlined in <i>Food Ideas to Help with Diarrhea During Chemotherapy</i>.*</p>
<p>Sore mouth may occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.</p>	<p>uncommon</p>	<ul style="list-style-type: none"> • Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. • Make a mouthwash with ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day. <p>Try the ideas in <i>Food Ideas for a Sore Mouth During Chemotherapy</i>.*</p>

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Hair loss may occur. If you lose hair, it will grow back once you stop treatment. Colour and texture may change.	very uncommon	If hair loss is a problem, refer to <i>For the Patient: Hair Loss Due to Chemotherapy</i> .*
Changes in hearing may occur.	common	Contact your doctor if you have any concerns in your hearing.
Tiredness and lack of energy may occur.	common	<ul style="list-style-type: none"> Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue</i>.*
Your skin may sunburn more easily than usual.		<ul style="list-style-type: none"> Refer to <i>Your Medication Sun Sensitivity and Sunscreens*</i> or the <i>BC Health Guide</i> for more information. After sun exposure, if you have a severe sunburn or skin reaction such as itching, rash, or swelling, contact your doctor.

***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 if 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 - Abbotsford 604-851-4710
- BC Cancer - Kelowna 250-712-3900
- BC Cancer - Prince George 250-645-7300
- BC Cancer - Surrey 604-930-4055
- 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.