



Provincial Health Services Authority

For the Patient: UHNAVPCPMB

Other Names: First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with PACLitaxel, CARBOplatin and Pembrolizumab

U = Undesignated (requires special approval)

HN = Head and Neck

AV = AdVanced

P = Paclitaxel

C = Carboplatin

PMB = PeMBrolizumab

ABOUT THIS MEDICATION

What are these drugs used for?

UHNAVPCPMB 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:

- 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.
- Paclitaxel is an anticancer drug that belongs to a group of drugs called taxanes. It works by preventing the replication of DNA that is needed for cancer cells to divide.
- Carboplatin is an anticancer drug that belongs to a group of drugs called platinum. It works by preventing the synthesis of DNA, RNA and proteins that are needed for cancer cells to divide.

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.
 - Paclitaxel is given next. The infusion lasts about 3 hours.
You will also be given intravenous drugs before paclitaxel to help prevent allergic reactions.
 - Carboplatin is given last. The infusion lasts about 30 minutes.

UHNAVPCMB TREATMENT PROTOCOL

Cycle 1: Start Date: _____

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pembrolizumab Paclitaxel Carboplatin	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment

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

What will happen while I am being treated?

- A blood test is done within one month of starting treatment.
- A blood test is also done before Day 1 of each cycle.
- The dose and timing of your treatment may be changed based on your blood test results and/or other side effects.
- Your very first treatment will take longer than other treatments because a nurse will be reviewing the possible side effects of your treatment plan and will discuss with you how to manage them. *It is a good idea to bring someone with you to your first treatment appointment.*
- Please bring your anti-nausea drugs with you for each treatment. Your nurse will tell you when to take them. You may also need to take anti-nausea drugs at home after treatment. It is easier to prevent nausea and vomiting than to treat it once it happens, so follow directions closely.

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 UHNAVPCPMB?

- 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.
- 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, paclitaxel, and carboplatin 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</p> <p>(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</p> <p>(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</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>Common</p> <p>(less than 1 in 10 but more than 1 in 100)</p>
<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>

SERIOUS SIDE EFFECTS	How common is it?
<p>Problems in the pancreas <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • abdominal pain • nausea and vomiting 	<p>Rare (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 (less than 1 in 1000 but more than 1 in 10000)</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>Rare (less than 1 in 1000 but more than 1 in 10000)</p>

Management of Other Side Effects

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
<p>Your white blood cells will decrease a few days after your treatment. They usually return to normal in 2-3 weeks. 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.</p>	<p>Very Common</p>	<p>To help prevent infection:</p> <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Take care of your skin and mouth by gently washing regularly. • 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.
<p>Your platelets may decrease during or after your treatment They will return to normal after your last treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual.</p>	<p>Very 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. • Avoid taking ASA (e.g. ASPIRIN®) or Ibuprofen (e.g. ADVIL®), <i>unless prescribed by your doctor.</i>
<p>Tiredness and lack of energy may sometimes occur.</p>	<p>Very Common</p>	<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> • If tiredness is persistent and you have other symptoms of hepatitis or inflammation of glands, tell your doctor as soon as possible. (see the table above for serious side effects.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Loss of appetite and weight loss sometimes occur.	Very Common	<ul style="list-style-type: none"> • Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>.* • If loss of appetite is persistent and you have other symptoms of hepatitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Hair loss is common and may begin within a few days or weeks of treatment. Your hair may thin or you may become totally bald. Your scalp may feel tender. You may lose hair on your face and body. Your hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.	Very Common	<ul style="list-style-type: none"> • Use a gentle shampoo and soft brush. • Care should be taken with use of hair spray, bleaches, dyes and perms. • Protect your scalp with a hat, scarf or wig in cold weather. Some extended health plans will pay part of the cost of a wig. • Cover your head or apply sunblock on sunny days. • Apply mineral oil to your scalp to reduce itching. • If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-rimmed hat and glasses.
Allergic reactions to paclitaxel often occur. Signs of an allergic reaction include flushing, rash, itching, swelling and breathing problems. These allergic reactions most often occur during the first hour of treatment.	Common	<ul style="list-style-type: none"> • Dexamethasone is used to prevent allergic reactions. You will be given dexamethasone before you receive paclitaxel. • You will also be given other drugs to help prevent an allergic reaction. One may make you drowsy. • Your nurse will monitor you for any signs that you may be developing an allergic reaction while receiving paclitaxel. • Tell your nurse or doctor immediately if you notice any of the listed symptoms.
Paclitaxel contains alcohol and may cause drowsiness .	Common	<ul style="list-style-type: none"> • Do not drive a car or operate machinery soon after treatment.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Fever may sometimes occur.	Common	<ul style="list-style-type: none"> • 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. • If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Headache may sometimes occur.	Common	<ul style="list-style-type: none"> • If headache is persistent and you have other symptoms of inflammation of glands, tell your doctor as soon as possible. (see the table above for serious side effects.)
Muscle or joint pain may occur a few days after your treatment.	Common	<ul style="list-style-type: none"> • Tell your doctor as soon as possible. (see the table above for serious side effects.)
Numbness or tingling of the fingers or toes may occur. This almost always returns to normal, slowly, once your treatments are over. This may take several months.	Common	<ul style="list-style-type: none"> • Be careful when handling items that are sharp, hot or cold. • Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects.
Nausea and vomiting may occur after your treatment and may last for 24 hours.	Common	<ul style="list-style-type: none"> • 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 to treat it once it has happened, so follow directions closely. • Eat and drink often in small amounts. • Try the ideas in “<i>Food Choices to Control Nausea</i>”.
Constipation may sometimes occur.	Common	<ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Suggestions for Dealing with Constipation</i>.* • If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
<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. <i>Mouth sores or bleeding gums can lead to an infection.</i></p>	Uncommon	<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. • Try soft, bland foods like puddings, milkshakes and cream soups. • Avoid spicy, crunchy or acidic food, and very hot or cold foods. • Call your doctor if you are having difficulty eating or drinking due to pain.
<p>Swelling of hands, feet or lower legs may occur if your body retains extra fluid</p>	Uncommon	<ul style="list-style-type: none"> • If swelling is a problem, elevate your feet when resting • Avoid tight clothing
<p>Pain or tenderness may occur where the needle was placed in your vein within 1-2 days after treatment. This may extend all the way up the arm. Sometimes pain may occur where the cancer is located.</p>	Uncommon	<ul style="list-style-type: none"> • Apply warm compresses or soak in warm water for 15-20 minutes several times a day. • <i>See your doctor if the pain continues to bother you.</i>
<p>Paclitaxel burns if it leaks under the skin</p>	Very Rare	<ul style="list-style-type: none"> • Tell your nurse <i>immediately</i> if you feel pain, burning, stinging, or any other change while the drug is being given.

***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

Rev Aug 2018



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.