

For the Patient: HNAVPMBM6

Other Names: Maintenance Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab

HN = Head and Neck
AV = AdVanced
PMB = PeMBrolizumab
M = Maintenance
6 = 6-Weekly

ABOUT THIS MEDICATION

What is this drug used for?

HNAVPMBM6 is an intravenous (through the vein) drug treatment for squamous cell head and neck cancer. It is given after your cancer has been treated with an initial treatment.

How does this drug work?

There is one drug 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.

INTENDED BENEFITS

This treatment is being given to keep the cancer from progressing, once it has been successfully controlled with an initial treatment. Research has shown that patients may have prolonged remission of their cancer, and may live longer after receiving this treatment.

TREATMENT SUMMARY

How is this drug given?

- This treatment will continue for a maximum of 2 years (counting from the start of your initial treatment that contains pembrolizumab) as long as you are benefiting from treatment and not having too many side effects.
- Each treatment cycle lasts 6 weeks (42 days).
- For each cycle, you will have one drug given to you intravenously (through the vein) on Day 1.
 - Pembrolizumab infusion lasts about 30 minutes.

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.*

HNAVPMBM6 TREATMENT PROTOCOL

Start Date: _____

Cycle 1:
Blood test before Day 1

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pembrolizumab	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
Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment
Day 29	Day 30	Day 31	Day 32	Day 33	Day 34	Day 35
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment
Day 36	Day 37	Day 38	Day 39	Day 40	Day 41	Day 42
No treatment	No treatment	No treatment	No treatment	No treatment	No treatment	No treatment

This 42-day cycle will occur for a maximum of 2 years (counting from the start of your initial treatment that contains pembrolizumab) as long as you are benefiting from treatment and not having too many side effects.

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 HNAVPMBM6?

- 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 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 20 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</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>
<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</p> <p>(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>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.)
<p>Loss of appetite and weight loss sometimes occur.</p>	<p>Very Common</p>	<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.)
<p>Nausea and vomiting may occur after your treatment. Most people have little or no nausea. Most people do not require anti-nausea drugs. Nausea may last longer for some patients (delayed nausea and vomiting).</p>	<p>Common</p>	<ul style="list-style-type: none"> • You may be given a prescription for anti-nausea drug(s) to take before your 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 fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Food Choices to Help Control Nausea</i>.* • Your doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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.)
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.)
Hair loss is rare.	Rare	<ul style="list-style-type: none"> • If hair loss is a problem, refer to <i>For the Patient: Hair Loss Due to Chemotherapy</i>.*
Pain or tenderness may occur where the needle was placed	Very Rare	<ul style="list-style-type: none"> • Apply cool compresses or soak in cool water for 15-20 minutes several times a day.

*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.