

For the Patient: BRAVPPN

Palliative Therapy for Metastatic Breast Cancer using Pembrolizumab and Paclitaxel NAB

BR = BREast

AV = AdVanced

P = Pembrolizumab

PN = Paclitaxel NAB

ABOUT THESE MEDICATIONS

What are these drugs used for?

- Pembrolizumab and nanoparticle, albumin-bound paclitaxel (paclitaxel NAB) are drugs given in the hope of destroying or stopping the growth of breast cancer cells that have spread in your body. This treatment may improve your overall survival and help reduce your cancer symptoms.

How do these drugs work?

- Pembrolizumab (pem" broe liz' ue mab) is a monoclonal antibody, a type of protein designed to help your own body's immune system target cancer cells to stop them from growing.
- Nanoparticle, albumin-bound paclitaxel (paclitaxel NAB) (pak" li tax' el nab) is an anticancer drug that works by interfering with the genetic material of replicating cells and preventing an increase in the number of cancer cells. It is often referred to as nab-paclitaxel.

INTENDED BENEFITS

- This therapy is given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay the onset of new symptoms.

TREATMENT SUMMARY

How are these drugs given?

- Each medication will be given directly into the vein, intravenously (IV).
- The treatment will be given in 'cycles'. Each cycle length is 3 weeks.
- Pembrolizumab and paclitaxel NAB will be given on Day 1 every 3 weeks.
- Treatment will take approximately one hour.

The calendar on the following page outlines your overall treatment plan:

| 1 C Y C L E | DATE | TREATMENT PLAN |
|----------------------------|------|--|
| | | Week 1 → Day 1: pembrolizumab and paclitaxel NAB |
| | | Week 2 → No treatment |
| | | Week 3 → No treatment |

This treatment will continue as long as you are benefitting from it and not having too many side effects, as determined by your oncologist, up to a maximum of 35 cycles of pembrolizumab.

What will happen when I get my drugs?

- You will see your clinician and will need to have a blood test before each treatment.
- The dose and timing of your treatment may be changed based on the 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 chemotherapy plan and will discuss with you how to manage them. *It is a good idea to bring someone with you to your first chemotherapy appointment.*

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. If other doctors are involved in your care it is important they know you are on these treatments and the autoimmune side effects they can cause.

INSTRUCTIONS:

- Tell your doctor if you have ever had an unusual or **allergic reaction** to any drugs including pembrolizumab, paclitaxel, human albumin, or paclitaxel NAB before starting this treatment
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of treatment.
- Pembrolizumab and paclitaxel NAB may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with these drugs, and for at least 4 months after the last dose of pembrolizumab. Tell your doctor right away if you or your partner becomes pregnant. **Do not breastfeed** during treatment and for at least 4 months after the last dose of pembrolizumab.
- Tell doctors, dentists and other health professionals that you are being treated with pembrolizumab and paclitaxel NAB before you receive any treatment from them. You should carry the BC Cancer **wallet card** for pembrolizumab to alert health providers.
- ***Do not receive any immunizations before discussing with your doctor***

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 significant medical conditions.

Medication Interactions:

- Other drugs may **interact** with pembrolizumab and paclitaxel NAB. Tell a member of your healthcare team if you are taking any other drugs as you may need extra blood tests or your dose(s) may need to be changed. Check with your doctor or pharmacist before you start or stop taking any new drugs including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Pembrolizumab 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?

- Pembrolizumab 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 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.

The following side effects were most frequently reported:

Very common (more than 1 in 10 people)

- diarrhea
- itching, rash
- joint pain
- feeling tired
- feeling less hungry
- cough

| 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 (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 (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 (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> |
| <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> |

| SERIOUS SIDE EFFECTS | How common is it? |
|--|--|
| Problems in other organs (nervous system, eyes) <i>Symptoms may include:</i> <ul style="list-style-type: none"> • tingling, numbness, lack of energy • changes in eyesight • dizziness | Common (less than 1 in 10 but more than 1 in 100) |
| 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 | Common (less than 1 in 10 but more than 1 in 100) |
| Inflammation of the liver (hepatitis) <i>Symptoms may include:</i> <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 | Uncommon (less than 1 in 100 but more than 1 in 1000) |
| Inflammation of the kidneys (nephritis) <i>Symptoms may include:</i> <ul style="list-style-type: none"> • changes in the amount or colour of your urine | Uncommon (less than 1 in 100 but more than 1 in 1000) |
| Problems in the pancreas <i>Symptoms may include:</i> <ul style="list-style-type: none"> • abdominal pain • nausea and vomiting | Rare (less than 1 in 1000 but more than 1 in 10000) |
| Infusion reactions <i>Symptoms may include:</i> <ul style="list-style-type: none"> • shortness of breath • itching or rash • dizziness • fever • wheezing • flushing • feeling like passing out | Rare (less than 1 in 1000 but more than 1 in 10000) |

Management of Other Side Effects

| SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|---|---|
| <p>Allergic reactions to pembrolizumab or paclitaxel NAB may rarely occur. Signs of an allergic reaction may include flushing, dizziness, swelling or breathing problems, fast or uneven heart beat, chest pain, rash, or itching.</p> <p>This can occur immediately or several hours after receiving pembrolizumab or paclitaxel NAB.</p> | <p>Tell your nurse if this happens while you are receiving treatment or contact your oncologist immediately if this happens after you leave the clinic.</p> |
| <p>Paclitaxel NAB burns if it leaks under the skin.</p> | <p>Tell your nurse or doctor immediately if you feel burning, stinging, or any other change while the drug is being given.</p> |
| <p>Pain or tenderness may occur where the needle was placed</p> | <p>Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</p> |
| <p>Your white blood cells may decrease after your treatment. They usually return to normal after your last 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.</p> | <p>To help prevent infection:</p> <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 healthcare team immediately at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine. |
| <p>Nausea and vomiting may occur after your treatment. Most people have little or no nausea.</p> | <p>You may 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.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.* |
| <p>Constipation may sometimes occur.</p> | <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of fluids. • Try ideas in <i>Food Choices to Manage Constipation</i>.* |
| <p>Loss of appetite sometimes occurs.</p> | <ul style="list-style-type: none"> • Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i>.* |

| SIDE EFFECTS DURING TREATMENT | MANAGEMENT |
|---|---|
| Muscle or joint pain may sometimes occur a few days after your treatment. | You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your doctor if the pain interferes with your activity. |
| Tiredness and lack of energy may sometimes occur. | <ul style="list-style-type: none"> Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i>.* |
| Numbness or tingling of the fingers or toes commonly occurs. This will slowly (over several weeks) return to normal once your treatments are over. | <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. |
| Swelling of hands, feet, or lower legs may rarely occur if your body retains extra fluid. | <p>If swelling is a problem:</p> <ul style="list-style-type: none"> Elevate your feet when sitting. Avoid tight clothing. |
| Hair loss is common with paclitaxel NAB and may begin within a few days or weeks of treatment. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair usually grows back once your treatments are over and sometimes between treatments. Colour and texture may change. | <p>Refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</i>.*</p> <p>You may also want to:</p> <ul style="list-style-type: none"> 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. |

***Please ask your chemotherapy nurse or pharmacist for a copy.**

THE FOLLOWING INFORMATION IS VERY IMPORTANT

SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty breathing, or fainting.
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Diarrhea or changes in bowel habits**; black, tarry stools; blood or mucous in the stool; severe abdominal pain
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.

- Signs of **kidney problems** such as lower back or side pain, blood in the urine, swelling of feet or lower legs, or change in amount or colour of urine.
- Signs of **blood sugar problems** such as thirst and frequent need to pass urine.

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. |