For the Patient: ULUAVNIV

Other Names: Treatment of Advanced Non-Small Cell Lung Cancer Using Nivolumab

U = Undesignated (requires special approval)
LU = Lung
AV = Advanced
NIV = NIVolumab

ABOUT THIS MEDICATION

What is this drug used for?
- Nivolumab (nye vol' ue mab) is a monoclonal antibody used for the treatment of non-small cell lung cancer (NSCLC). It is usually given after you have had at least one other type of chemotherapy.

How does this drug work?
- Nivolumab is a type of protein designed to target and interfere with the growth of cancer cells in your body.

INTENDED BENEFITS
This treatment is being given 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

How is this drug given?
- Nivolumab is given as an infusion (injection) into a vein. The infusion will last about 30 minutes. You will have an infusion every 2 weeks. This 2 weeks period is called a cycle.

What will happen when I get this drug?
- A blood test is done before starting each treatment cycle. You will see your oncologist at least every 2 weeks, before treatments.
- The dose of your treatment may be changed based on your blood test results and/or other side effects.
OTHER INSTRUCTIONS

- *It is very important to report side effects immediately to your doctor.* Do not manage side effects at home without 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 nivolumab?

- Other drugs may interact with nivolumab. 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 nivolumab.

Other important things to know:

- **Before you are given nivolumab**, 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.
  - had an organ transplant, such as a kidney transplant.
  - have any other medical conditions.
- Nivolumab may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with nivolumab and for at least 5 months after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
- Nivolumab may pass into your breast milk. **Do not breastfeed** during treatment.
- **Tell** doctors or dentists that you are being treated with nivolumab before you receive any treatment from them.
SIDES EFFECTS AND WHAT TO DO ABOUT THEM

Nivolumab 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?
- Nivolumab 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 nivolumab.
- 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
<table>
<thead>
<tr>
<th>SERIOUS SIDE EFFECTS</th>
<th>How common is it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inflammation of the intestines (colitis)</strong></td>
<td>Common</td>
</tr>
<tr>
<td>Symptoms may include:</td>
<td>(less than 1 in 10 but more than 1 in 100)</td>
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<tr>
<td>• diarrhea (loose stools) or more bowel movements than usual. <strong>Do not treat the diarrhea yourself.</strong></td>
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<td>• blood or mucus in stools or dark, tarry, sticky stools</td>
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<tr>
<td>• severe stomach pain (abdominal pain) or tenderness</td>
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<tr>
<td><strong>Inflammation of the thyroid gland (hyperthyroidism, hypothyroidism)</strong></td>
<td>Common</td>
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<tr>
<td>Symptoms may include:</td>
<td>(less than 1 in 10 but more than 1 in 100)</td>
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<td>• rapid heart beat</td>
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<td>• weight loss or gain</td>
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<tr>
<td>• increased sweating</td>
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<tr>
<td>• hair loss</td>
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<tr>
<td>• feeling cold</td>
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<td>• constipation or diarrhea</td>
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<td>• your voice gets deeper</td>
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<tr>
<td>• muscle aches</td>
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<td>• changes in sleep patterns</td>
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<tr>
<td><strong>Inflammation of the pituitary gland (hypophysitis, hypopituitarism, including secondary adrenal insufficiency)</strong></td>
<td>Common</td>
</tr>
<tr>
<td>Symptoms may include:</td>
<td>(less than 1 in 10 but more than 1 in 100)</td>
</tr>
<tr>
<td>• weight loss</td>
<td></td>
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<tr>
<td>• increased sweating, hot flashes</td>
<td></td>
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<tr>
<td>• hair loss (includes facial and pubic)</td>
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<tr>
<td>• feeling cold</td>
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<tr>
<td>• headaches that will not go away or unusual headache</td>
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<td>• decreased sex drive</td>
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<td>• vision problems</td>
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<td>• excessive thirst and urination</td>
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## SERIOUS SIDE EFFECTS

<table>
<thead>
<tr>
<th>SERIOUS SIDE EFFECTS</th>
<th>How common is it?</th>
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</thead>
</table>
| **Inflammation of the lungs (pneumonitis)**  
*Symptoms may include:*  
• shortness of breath  
• chest pain  
• coughing | Common  
(less than 1 in 10 but more than 1 in 100) |
| **Problems with muscles**  
*Symptoms may include:*  
• back pain  
• spasms  
• weakness  
• muscle pain | Common  
(less than 1 in 10 but more than 1 in 100) |
| **Skin problems**  
*Symptoms may include:*  
• rash  
• dry skin | Common  
(less than 1 in 10 but more than 1 in 100) |
| **Problems in other organs (nervous system, eyes)**  
*Symptoms may include:*  
• tingling, numbness, lack of energy  
• changes in eyesight  
• dizziness | Common  
(less than 1 in 10 but more than 1 in 100) |
| **Inflammation of the liver (hepatitis)**  
*Symptoms may include:*  
• 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)**  
*Symptoms may include:*  
• changes in the amount or colour of your urine | Uncommon  
(less than 1 in 100 but more than 1 in 1000) |
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<th>SERIOUS SIDE EFFECTS</th>
<th>How common is it?</th>
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<tbody>
<tr>
<td><strong>Problems in the pancreas</strong> &lt;br&gt; Symptoms may include:  &lt;br&gt; • abdominal pain  &lt;br&gt; • nausea and vomiting</td>
<td><strong>Rare</strong> &lt;br&gt; (less than 1 in 1000 but more than 1 in 10000)</td>
</tr>
<tr>
<td><strong>Blood sugar problems (type 1 diabetes mellitus)</strong> &lt;br&gt; Symptoms may include:  &lt;br&gt; • hunger or thirst  &lt;br&gt; • a need to urinate more often  &lt;br&gt; • weight loss</td>
<td><strong>Rare</strong> &lt;br&gt; (less than 1 in 1000 but more than 1 in 10000)</td>
</tr>
<tr>
<td><strong>Infusion reactions</strong> &lt;br&gt; Symptoms may include:  &lt;br&gt; • shortness of breath  &lt;br&gt; • itching or rash  &lt;br&gt; • dizziness  &lt;br&gt; • fever  &lt;br&gt; • wheezing  &lt;br&gt; • flushing  &lt;br&gt; • feeling like passing out</td>
<td><strong>Rare</strong> &lt;br&gt; (less than 1 in 1000 but more than 1 in 10000)</td>
</tr>
<tr>
<td>OTHER SIDE EFFECTS</td>
<td>How common is it?</td>
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<td><strong>Pain or tenderness</strong> may occur where the needle was placed.</td>
<td>Very rare</td>
</tr>
</tbody>
</table>
| **Nausea and vomiting** may occur after your treatment. Most people have little or no nausea. | Common | • You may be given a prescription for antinausea 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.  
  o Drink plenty of fluids.  
  o Eat and drink often in small amounts.  
• Try the ideas in *Food Choices to Help Control Nausea.*  
• If nausea and vomiting is persistent and you have other symptoms of **hepatitis**, tell your doctor as soon as possible. (see the table above for serious side effects.) |
| **Fever** may sometimes occur. | Common | • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day.  
• If you have other symptoms of **colitis**, tell your doctor as soon as possible. (see the table above for serious side effects.) |
| **Constipation** may sometimes occur. | Common | • Exercise if you can.  
• Drink plenty of fluids.  
• Try ideas in *Suggestions for Dealing with Constipation.*  
• 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 | • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.  
• If headache is persistent and you have other symptoms of **inflammation of glands or Inflammation of the nerves**, tell your doctor as soon as possible. (see the table above for serious side effects.) |
### OTHER SIDE EFFECTS

<table>
<thead>
<tr>
<th><strong>Loss of appetite and weight loss</strong> sometimes occur.</th>
<th><strong>How common is it?</strong></th>
<th><strong>MANAGEMENT</strong></th>
</tr>
</thead>
</table>
|                                                      | Very common            | • Try the ideas in *Food Ideas to Help with Decreased Appetite.*  
• 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.) |

<table>
<thead>
<tr>
<th><strong>Tiredness</strong> and lack of energy may sometimes occur.</th>
<th><strong>How common is it?</strong></th>
<th><strong>MANAGEMENT</strong></th>
</tr>
</thead>
</table>
|                                                      | Very common            | • Do not drive a car or operate machinery if you are feeling tired.  
• Try the ideas in *Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.*  
• 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.) |

<table>
<thead>
<tr>
<th><strong>Hair loss</strong> is rare with nivolumab.</th>
<th><strong>How common is it?</strong></th>
<th><strong>MANAGEMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rare</td>
<td>If hair loss is a problem, refer to <em>For the Patient: Hair Loss Due to Chemotherapy.</em></td>
</tr>
</tbody>
</table>

*Please ask your oncologist 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:___________________
### MEDICAL ALERT

**NAME _______________________________**

has received **CHECKPOINT INHIBITOR IMMUNOTHERAPY:**

Immune-Mediated Adverse Reactions

ALWAYS CARRY THIS CARD AND SHOW TO PHYSICIANS INCLUDING ANESTHETISTS

<table>
<thead>
<tr>
<th>SEVERE IMMUNE-MEDIATED ADVERSE REACTIONS</th>
<th>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.</th>
</tr>
</thead>
</table>
| 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 |
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.
<table>
<thead>
<tr>
<th>BC CANCER CENTRES</th>
<th>CONTACT INFORMATION AND PROCESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbotsford</td>
<td>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).</td>
</tr>
<tr>
<td>Kelowna</td>
<td>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.</td>
</tr>
<tr>
<td>Prince George</td>
<td>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).</td>
</tr>
<tr>
<td>Surrey</td>
<td>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.</td>
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<tr>
<td>Vancouver</td>
<td>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.</td>
</tr>
<tr>
<td>Victoria</td>
<td>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.</td>
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