

For the Patient: UHNAVIV4

Other Names: Treatment of Platinum-refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck Using 4-Weekly Nivolumab

U = Undesignated

HN = Head and Neck

AV = Advanced

NIV = Nivolumab

ABOUT THIS MEDICATION

What is this drug used for?

- Nivolumab (nye vol' ue mab) is a drug that is used to treat head and neck cancers, that has spread to other parts of the body or cannot be removed by surgery.

How does this drug work?

- Nivolumab is a type of protein to help your immune system attack and destroy cancer cells.

INTENDED BENEFITS

- Nivolumab is given to destroy and/or slow down the growth of cancer cells.
- It may improve your current symptoms, and delay or prevent the onset of new symptoms.

TREATMENT SUMMARY

How is this drug given?

- Nivolumab is given intravenously (via the vein) over 30 minutes.
- You will be treated with nivolumab once every 4 weeks. This 4 week period is called a "cycle". The cycle is repeated as long as you are benefiting from treatment and not having too many side effects.

What will happen while I am being treated?

- A blood test is done before starting each treatment cycle at the time you see your oncologist. The dose and timing of your chemotherapy may be changed based on your blood counts and / or other side effects.
- You may have a **transient worsening of disease** before the tumour shrinks. Tumour response will be assessed during treatment.

INSTRUCTIONS FOR THE PATIENT

- ***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.***
- Before you are given nivolumab, inform 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 weaken your immune system, such as steroids, like 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. You must use **birth control** while being treated with nivolumab and for at least 4 months after your last dose. Tell your doctor right away if you or your partner becomes pregnant.
- Nivolumab may pass into breast milk. **Do not breastfeed** during treatment.
- Tell doctors or dentists you are being treated with nivolumab before you receive any treatment from them.

What other drugs or foods can interact with Nivolumab?

- Medicines that weaken your immune system, such as steroids, may decrease the benefit of nivolumab.
- Inform your doctor or pharmacist of all the medications you are taking, including all prescription and non-prescription medicines, vitamins, minerals, dietary supplements, herbal or natural health products. These may interfere with your treatment or cause side effects you are not aware of.
- The drinking of alcohol, in small amounts, does not appear to affect the safety or benefit of nivolumab.

What are the side effects of Nivolumab, how often do they occur, and how do I manage them?

- 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.
- Nivolumab can cause **serious side effects** in many parts of your body. These side effects are most likely to begin during your treatment; however, side effects can show up months after your last treatment with nivolumab.
- It is very important to tell your doctor immediately if you have, or develop, any of the symptoms listed under **Serious Side Effects**. **Do not try to treat or diagnose symptoms yourself**. Informing your oncologist *immediately* may prevent the problem from becoming more serious.

SIDE 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

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 	common
<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 	common
<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 	common

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 	common
<p>Problems with muscles <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • back pain • spasms • weakness • muscle pain 	common
<p>Skin problems <i>Symptoms may include:</i></p> <ul style="list-style-type: none"> • rash • dry skin 	common
<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 	common
<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 	uncommon
<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 	uncommon

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 	rare
<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 	rare
<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 	rare

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	very rare	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Nausea and vomiting may occur after your treatment. Most people have little or no nausea.	uncommon	<p>It is easier to prevent nausea than treat it once it has occurred.</p> <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • If given a prescription for anti-nauseants, take prescribed anti-nauseant regularly. <p>Try the ideas in <i>Food Choices to Help Control Nausea</i>.*</p> <ul style="list-style-type: none"> • If nausea and vomiting persist and you have other symptoms of hepatitis, tell your doctor as soon as possible.
Fever may sometimes occur.	common	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. • If you have other symptoms of colitis, tell your doctor as soon as possible.
Constipation may sometimes occur.	common	<ul style="list-style-type: none"> • Exercises 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.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Headache may sometimes occur.	common	<ul style="list-style-type: none"> • Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. • If headache persists and you have other symptoms of inflammation of glands or inflammation of the nerves, tell your doctor as soon as possible.
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.
Tiredness and lack of energy may sometimes occur	very 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>*. • If tiredness persists and you have other symptoms of hepatitis, or inflammation of glands, tell your doctor as soon as possible.
Hair loss is rare with nivolumab	rare	If hair loss is a problem, refer to <i>For the Patient: Hair Loss due to Chemotherapy</i> *

*Please ask your 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: _____