

For the Patient: LUAVPCIPNI

Other Names: First-LineTreatment of Advanced Squamous Non-Small Cell Lung Cancer with Paclitaxel, Carboplatin, Ipilimumab and Nivolumab

LU = LUng
AV = AdVanced
P = Paclitaxel
C = Carboplatin
IP = IPilimumab
NI = NIvolumab

ABOUT THIS MEDICATION

What are these drugs used for?

LUAVPCIPNI 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:

- Ipilimumab and nivolumab are a type of therapy called immunotherapy. They are antibodies 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 platinums. 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 take drug(s) 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.

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How are these drugs given?

Your treatment plan consists of 2 parts. The first part consists of 2 cycles given 3 weeks (21 days) apart.

- For cycle 1, you will have the four drugs given to you intravenously (through the vein) on day 1.
 - Nivolumab is given first. The infusion lasts about 30 minutes.
 - Ipilimumab is given second. The infusion lasts about 30 minutes.
 - Paclitaxel is given next. The infusion lasts about 3 hours (180 minutes).
 You will also be given intravenous drugs before paclitaxel to help prevent allergic reactions.
 - Carboplatin is given last. The infusion lasts about 30 minutes.
- For cycle 2, you will have three drugs given to you intravenously on day 1.
 - Nivolumab is given first. The infusion lasts about 30 minutes.
 - Paclitaxel is given next. The infusion lasts about 3 hours (180 minutes).
 You will also be given intravenous drugs before paclitaxel to help prevent allergic reactions.
 - Carboplatin is given last. The infusion lasts about 30 minutes.

The second part begins 3 weeks after cycle 2.

- Starting with cycle 3, your treatment plan consists of cycles which last 6 weeks (42 days). In each cycle you will receive treatment every 3 weeks (on days 1 and 22).
 - On day 1, you will receive ipilimumab and nivolumab.
 - On day 22, you will receive nivolumab only.
 - Ipilimumab will be given as an infusion lasting about 30 minutes. The nivolumab infusion will be given over 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 each treatment day.
- 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. 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. Early treatment of side effects is critical.

What other drugs or foods can interact with LUAVPCIPNI?

- 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 nonprescription 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 ipilimumab or nivolumab, talk to your doctor if you:
 - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, rheumatoid arthritis, multiple sclerosis, lupus 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 liver damage from diseases or drugs
 - 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 at least 5 months after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Ipilimumab and nivolumab may pass into your breast milk. **Do not breastfeed** during treatment.
- Tell all doctors including dentists you see that you are being treated with ipilimumab, nivolumab, paclitaxel, and carboplatin before you receive treatment of any form. You should carry the BC Cancer <u>wallet card</u> for ipilimumab and nivolumab to alert health providers.
- Do not receive any immunizations before discussing with your doctor

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 drugs in your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Ipilimumab and nivolumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.
- These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment.
- **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
- · feeling nauseous
- fever

Serious Side Effects Associated with Ipilimumab and Nivolumab

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the INTESTINES (colitis)	Very Common
Symptoms may include	
 diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself. 	(more than 1 in 10)
blood in stools or dark, tarry, sticky stools	
stomach pain (abdominal pain) or tenderness	
• fever	
Inflammation of the THYROID GLAND (hyperthyroidism, hypothyroidism)	Very Common
Symptoms may include:	
rapid heart beat	(more than 1 in 10)
weight loss or gain	
increased sweating	
• hair loss	
feeling cold	
constipation or diarrhea	
your voice gets deeper	
muscle aches	
changes in sleep patterns	
Inflammation of the SKIN	Very Common
Symptoms may include	
rash on your skin, mouth blisters, dry or peeling skin	(more than 1 in 10)
Depigmentation of the SKIN (vitiligo)	Common

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SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the LUNGS (pneumonitis)	Very Common
Symptoms may include:	
shortness of breath	(more than 1 in 10)
chest pain	
• coughing	
Problems with MUSCLES	Very Common
Symptoms may include:	
back pain	(more than 1 in 10)
• spasms	
• weakness	
muscle pain	
Inflammation of the NERVES	Common
Symptoms may include	
weakness of legs, arms or face	(less than 1 in 10 but
numbness or tingling in hands or feet	more than 1 in 100)
lack of energy or dizziness	
Inflammation of certain GLANDS (pituitary, adrenal glands so they do not make enough	Common
hormone.	
Symptoms may include:	(less than 1 in 10 but
weight loss	more than 1 in 100)
increased sweating, hot flashes	
hair loss (includes facial and pubic)	
• feeling cold	
headaches that will not go away or unusual headache	
changes in behavior such as less sex drive, being irritable or forgetful vision problems, distributes or fainting	
 vision problems, dizziness or fainting excessive thirst and urination 	
excessive thirst and urmation unusual tiredness or sleepiness	
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SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the EYES Symptoms may include	Common
 changes in eyesight, blurry vision, double vision, or other vision problems eye pain or redness 	(less than 1 in 10 but more than 1 in 100)
Inflammation of the KIDNEYS (nephritis) Symptoms may include:	Common
changes in the amount or colour of your urine	(less than 1 in 10 but more than 1 in 100)
Infusion reaction. Symptoms may include	Common
 shortness of breath, wheezing or trouble breathing, cough, chest tightness dizziness, fainting, rapid or weak heartbeat itching, rash, hives, or feeling warm or flushed swelling of the throat, tongue, or face hoarse voice, throat tightness or trouble swallowing 	(less than 1 in 10 but more than 1 in 100)
Inflammation of the LIVER (hepatitis) Symptoms may include	Uncommon
 yellowing of your skin or the whites of your eyes, dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach, or bruise easily 	(less than 1 in 100 but more than 1 in 1000)
Problems in the PANCREAS	Rare
 Symptoms may include: abdominal pain nausea and vomiting 	(less than 1 in 1000 but more than 1 in 10000)

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SERIOUS SIDE EFFECTS	How common is it?
Blood sugar problems (type 1 diabetes mellitus) Symptoms may include:	Rare
 hunger or thirst a need to urinate more often weight loss 	(less than 1 in 1000 but more than 1 in 10000)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Rare	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Nausea does not usually occur.	Rare	
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)
Tiredness and lack of energy may sometimes occur.	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)

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OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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)
Constipation may sometimes occur.	Rare	 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)
Loss of appetite and weight loss sometimes occur.	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)
Hair loss is rare with ipilimumab and nivolumab.	Uncommon	If hair loss is a problem, refer to For the Patient: Hair Loss Due to Chemotherapy.*

Management of Other Side Effects

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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.	Very Common	 To help prevent infection: 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 <i>immediately</i> at the first sign of an <i>infection</i> such as fever (over 100°F or 38°C by an oral thermometer), chills, cough or burning when you pass urine.

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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.	Very Common	 To help prevent bleeding problems: 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®), unless prescribed by your doctor.
Tiredness and lack of energy may sometimes occur.	Very Common	 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.)
Loss of appetite and weight loss sometimes occur.	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.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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	 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	 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 <i>immediately</i> if you notice any of the listed symptoms.
Paclitaxel contains alcohol and may cause drowsiness .	Common	Do not drive a car or operate machinery soon after treatment.
Fever may sometimes occur.	Common	 Call your doctor <i>immediately</i> at the first sign of an <i>infection</i> 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.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Headache may sometimes occur.	Common	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	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	 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	 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 "Food Choices to Control Nausea".
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.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
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. Mouth sores or bleeding gums can lead to an infection.	Uncommon	 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.
Swelling of hands, feet or lower legs may occur if your body retains extra fluid	Uncommon	 If swelling is a problem, elevate your feet when resting Avoid tight clothing
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.	Uncommon	 Apply warm compresses or soak in warm water for 15-20 minutes several times a day. See your doctor if the pain continues to bother you.
Paclitaxel burns if it leaks under the skin	Very Rare	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 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:				

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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	
BC Cancer - Victoria	250-519-5500
www.bccancer.bc.ca/health-professionals/professional-res	
Rev Aug 2018	



PERCENTAGE Health Services Authority				
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 Systemic Therapy Program
Developed: 28 Nov 2017 Revised:
www.bccancer.bc.ca
Provincial Health Services Authority

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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.

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