

For the Patient: LUSCDURPE (Carboplatin Option)

Other Names: Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Durvalumab, Platinum and Etoposide

LU = LUng
SC = Small Cell
DUR = DURvalumab
PE = CarboPlatin, **E**toposide

ABOUT THIS MEDICATION

What are these drugs used for?

Durvalumab (dur val' ue mab) is a type of therapy called immunotherapy. Carboplatin (KAR-boe-plat-in) and etoposide (ee-TOP-aw-side) are anticancer medications used for many types of cancer.

These medications are given intravenously (through the vein).

How do these drugs work?

Durvalumab is an antibody designed to help your own body's immune system target cancer cells to stop them from growing.

Carboplatin and etoposide are anticancer drugs that work by preventing the synthesis of DNA that is needed for cancer cells to divide.

INTENDED BENEFITS

This treatment is being given to destroy and/or 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 can also delay or prevent new symptoms from starting.

TREATMENT SUMMARY

How are these drugs given?

- Your treatment plan starts with 4 combination immunotherapy and chemotherapy "cycles". Each cycle lasts 3 weeks (21 days).

- For each of your first 4 cycles, you will have three medications given to you intravenously (through the vein) on Day 1, and one medication given to you intravenously on Days 2 and 3.
 - Day 1:
 - Durvalumab is given first, over approximately one hour (60 minutes)
 - Carboplatin is given second, over approximately half-an-hour (30 minutes).
 - Etoposide is given third, over approximately three-quarters-of-an-hour to one-and-a-half hours (45-90 minutes).
 - Days 2 and 3:
 - Only etoposide is given on these days and is given intravenously over approximately three-quarters-of-an-hour to one-and-a-half hours (45-90 minutes).

- After cycle 4 is completed, you will receive ongoing cycles of immunotherapy cycles. Each cycle lasts 4 weeks (28 days).
 - You will have only one medication given to you intravenously on Day 1.
 - Day 1: Durvalumab is given over approximately one hour (60 minutes)

The calendar outlines your overall treatment plan.

Cycles 1 to 4

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Durvalumab, Carboplatin & Etoposide	Etoposide	Etoposide	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

This 21-day cycle will repeat 4 times, then you will start the next part of your treatment:

Cycles 5 and beyond:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Durvalumab	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

This 28-day cycle will repeat until your treatment is completed, as determined by your oncologist.

What will happen when I get my drugs?

- A blood test is done within one month of starting treatment.
- A blood test is also done each cycle, on or before the first day of each cycle. The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects.
- You will see a physician or nurse practitioner every 3 or 4 weeks, before each cycle.
- 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.
- You will be given a prescription for anti-nausea medications (to be filled at your regular pharmacy). Please bring your anti-nausea medications with you for each treatment. Your nurse will tell you when to take the anti-nausea medication.
- You will also need to take your anti-nausea drugs at home after therapy. It is easier to prevent nausea than to treat it once it has occurred, 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.

What other drugs or foods can interact with durvalumab?

- Other drugs may **interact** with durvalumab. 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 durvalumab.

Other important things to know:

Before you are given durvalumab, 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.
- Durvalumab may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with durvalumab and for at least **3 months** after the last dose. Tell your doctor right away if you or your partner becomes pregnant.

- Durvalumab may pass into your breast milk. **Do not breastfeed** during treatment and for at least **3 months** after the last dose.
- **Tell** doctors or dentists that you are being treated with durvalumab before you receive any treatment from them.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Durvalumab 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?

- Durvalumab 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 durvalumab.
- **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)

- Cough
- Upper respiratory tract infection
- rash
- diarrhea
- fever

Serious Side Effects Associated with Durvalumab

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

SERIOUS SIDE EFFECTS	How common is it?
<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
<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 	Common

SERIOUS SIDE EFFECTS	How common is it?
<p>Infusion reactions</p> <p><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>Uncommon</p>

SIDE EFFECTS DURING TREATMENT	MANAGEMENT
<p>Allergic reactions may very rarely occur. Signs of an allergic reaction are dizziness, feeling faint, confusion, shortness of breath, and wheezing. This may occur immediately or several hours after receiving the drugs. It can occur after the first dose, or after many doses.</p>	<p>Tell your nurse if this happens while you are receiving the drugs or contact your doctor immediately if this happens after you leave the clinic</p>
<p>Etoposide burns if it leaks under the skin.</p>	<p>Tell your nurse immediately if you feel pain, burning, stinging, or any other change while the drug is being given.</p>
<p>Dizziness or feeling faint may occur during administration of etoposide.</p>	<p>Tell your nurse or doctor <i>immediately</i>.</p> <ul style="list-style-type: none"> • Lie down or sit with your feet elevated.
<p>Your white blood cells will 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. • Take care of your skin and mouth. • 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.
<p>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.</p>	<p>To help prevent bleeding problems:</p> <ul style="list-style-type: none"> • 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. Some medications such as ASA (e.g. ASPIRIN®) or ibuprofen (e.g. ADVIL®) may increase your risk of bleeding. • Do not stop taking any medication that has been prescribed by your doctor (e.g. ASA for your heart). • For minor pain, try acetaminophen (e.g. TYLENOL®) first, but occasional use of ibuprofen may be acceptable
<p>Nausea and vomiting may occur after your treatment and may last for up to 24 hours. Nausea may last longer for some patients.</p>	<p>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.</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts.

	<ul style="list-style-type: none"> • Try the ideas in <i>“Food Choices to Control Nausea”</i>.* <p>Your doctor may manage delayed nausea and vomiting differently. Be sure to let your doctor know if you experience this.</p>
<p>Sore mouth may occur during treatment. This is common. 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.</p>	<ul style="list-style-type: none"> • 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. • Try ideas in <i>‘Easy to Chew, Easy to Swallow Food Ideas’</i>.*.
<p>Constipation or diarrhea may occur.</p>	<p>To help constipation:</p> <ul style="list-style-type: none"> • Exercise if you can. • Drink plenty of liquids (8 cups a day). • Try ideas in <i>“Suggestions for Dealing with Constipation”</i>.* <p>To help diarrhea:</p> <ul style="list-style-type: none"> • Drink plenty of liquids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>“Food Ideas to Help with Diarrhea”</i>.*
<p>Tiredness or lack of energy may occur.</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>Pain or tenderness may occur where the needle was placed in your vein.</p>	<p>Apply cool compresses or soak in cool water for 15-20 minutes several times a day.</p>
<p>Loss of appetite and weight loss may occur</p>	<p>Try the ideas in <i>“Nutrition and Lung Cancer”</i>* and <i>“Food ideas to Help with Poor Appetite”</i>*.</p>
<p>Sugar control may sometimes be affected in diabetic patients.</p>	<p>Check your blood sugar regularly if you are diabetic. Tell your doctor if your blood sugars are not controlled.</p>

<p>Muscle or joint pain may sometimes occur.</p>	<ul style="list-style-type: none"> • 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 or does not go away.
<p>Taste alteration may occur</p>	<p>Try the ideas in <i>“Food Ideas to Cope with Taste and Smell Changes”</i>*</p>
<p>Hair loss can occur 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.</p>	<ul style="list-style-type: none"> • Use a gentle shampoo and soft brush. • Care should be taken with use of hair spray, bleaches, dyes, perms. • Protect your scalp with a hat, scarf or wig in cold weather. • Cover your head or apply sunblock on sunny days. • Apply mineral oil to your scalp to reduce itching.

***Please ask your chemotherapy nurse, dietitian, or pharmacist for a copy**

INSTRUCTIONS FOR THE PATIENT

What other drugs can interact with the treatment?

- Other drugs such as phenytoin (**Dilantin®**), atovaquone (**MEPRON®**), warfarin (**Coumadin®**), glucosamine and St John’s Wort may interact with treatment. Tell your doctor if you are taking these or other drugs as you may need extra blood tests, your dose may need to be changed or your treatment may need to be held for a few days.
- Check with your doctor or pharmacist before you start taking any new prescription or non-prescription drugs.

Other important things to know:

- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
- This treatment may cause sterility in men and menopause in women. If you plan to have children, discuss this with your doctor 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. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Tell all doctors or dentists you see that you being treated with durvalumab, carboplatin and etoposide before you receive treatment of any form.

THE FOLLOWING INFORMATION IS VERY IMPORTANT

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

- Signs of an **allergic reaction** soon after a treatment including dizziness, fast heartbeat, face swelling or breathing problems.
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer); chills, cough, pain or burning when you pass urine.
- Signs of **bleeding problems** such as black, tarry stools, blood in urine, pinpoint red spots on skin, extensive bruising.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath, or difficulty in breathing, swelling of ankles, or fainting.

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 - 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

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.