

#### For the Patient: LUSCDURPE

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

LU = LUng SC = Small Cell **DUR** = DURvalumab PE = CisPlatin, Etoposide

## **ABOUT THIS MEDICATION**

## What are these drugs used for?

Durvalumab (dur val' ue mab) is a type of therapy called immunotherapy. Cisplatin (sis-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.

Cisplatin 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).

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- For each of your first 4 cycles, you will have three medications given to you intravenously (through the vein) on Day 1, and two medications given to you intravenously on Days 2 and 3.
  - Day 1:
    - Durvalumab is given first, over approximately one hour (60 minutes)
    - Cisplatin is given second, over approximately half-an-hour (20-30 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:
    - Cisplatin is given first, over approximately half-an-hour (20-30 minutes).
    - Etoposide is given second, 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,	Cisplatin &	Cisplatin &	No	No	No	No
Cisplatin &	Etoposide	Etoposide	treatment	treatment	treatment	treatment
Etoposide						
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No treatment	No	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	treatment
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No treatment	No	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	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	No	No	No	No	No
	treatment	treatment	treatment	treatment	treatment	treatment
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
No	No	No	No	No	No	No
treatment	treatment	treatment	treatment	treatment	treatment	treatment
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
No	No	No	No	No	No	No
treatment	treatment	treatment	treatment	treatment	treatment	treatment
Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
No	No	No	No	No	No	No
treatment	treatment	treatment	treatment	treatment	treatment	treatment

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

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#### 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 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 durvalumab.

### Other important things to know:

Before you are given durvalumab, talk to your doctor or pharmacist if you:

- o 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.
- o take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.
- o had an organ transplant, such as a kidney transplant.
- o 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.

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- 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

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# <u>Serious Side Effects Associated with Durvalumab</u>

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the LUNGS (pneumonitis)	Very Common
Symptoms may include:	
shortness of breath	
chest pain	
• coughing	
Problems with muscles	Very Common
Symptoms may include:	
back pain	
• spasms	
weakness	
muscle pain	
Skin problems	Very Common
Symptoms may include:	
• rash	
• dry skin	
Inflammation of the INTESTINES (colitis)	Common
Symptoms may include:	
<ul> <li>diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea yourself.</li> </ul>	
blood or mucus in stools or dark, tarry, sticky stools	
severe stomach pain (abdominal pain) or tenderness	
Inflammation of the LIVER (hepatitis)	Common
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	

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SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the THYROID GLAND (hyperthyroidism, hypothyroidism)	Common
Symptoms may include:	
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	
Inflammation of the PITUITARY GLAND (hypophysitis, hypopituitarism, including secondary	Common
adrenal insufficiency)	
Symptoms may include:	
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	
Inflammation of the KIDNEYS (nephritis)	Common
Symptoms may include:	
changes in the amount or colour of your urine	

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SERIOUS SIDE EFFECTS	How common is it?
Infusion reactions	Uncommon
Symptoms may include:	
shortness of breath	
itching or rash	
dizziness	
• fever	
wheezing	
flushing	
feeling like passing out	

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SIDE EFFECTS DURING TREATMENT	MANAGEMENT
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.	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
Cisplatin and etoposide <b>burn</b> if they leak under the skin.	Tell your nurse <i>immediately</i> if you feel pain, burning, stinging, or any other change while the drug is being given.
Dizziness or feeling faint may occur during administration of etoposide.  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.	Tell your nurse or doctor immediately.  • Lie down or sit with your feet elevated.  To help prevent infection:  • 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.
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.	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. 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
Nausea and vomiting may occur after your treatment and may last for up to 24 hours. Nausea may last longer for some patients.	You will be given a prescription for antinausea 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.  • Drink plenty of liquids.  • Eat and drink often in small amounts.

• Try the ideas in <i>"Food Choices to Control Nausea".</i> * Your doctor may manage delayed nausea
Your doctor may manage delayed nausea
and vomiting differently. Be sure to let your
doctor know if you experience this.
<b>Sore mouth</b> may occur during treatment. • Brush your teeth gently after eating and at
This is common. Mouth sores can occur bedtime with a very soft toothbrush. If your
on the tongue, the sides of the mouth or in   gums bleed, use gauze instead of a brush.
the throat. <b>Mouth sores or bleeding</b> Use baking soda instead of toothpaste.
<b>gums can lead to an infection.</b> • 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 'Easy to Chew, Easy to
Swallow Food Ideas*.
Constipation or diarrhea may occur. To help constipation:
• Exercise if you can.
Drink plenty of liquids (8 cups a day).
Try ideas in "Suggestions for Dealing with
Constipation"*
To help diarrhea:
Drink plenty of liquids.
• Eat and drink often in small amounts.
Avoid high fibre foods as outlined in "Food"
Ideas to Help with Diarrhea"*
<b>Tiredness</b> or lack of energy may occur. • Do not drive a car or operate machinery if
you are feeling tired.
• Try the ideas in <i>Your Bank to Energy</i>
Savings: Helping People with Cancer Handle
Fatigue*
If tiredness is persistent and you have othe
symptoms of hepatitis or inflammation of
glands, tell your doctor as soon as possible.
(see the table above for serious side effects.
Pain or tenderness may occur where the Apply cool compresses or soak in cool water
needle was placed in your vein. for 15-20 minutes several times a day.
Loss of appetite and weight loss may Try the ideas in "Nutrition and Lung Cancer"
occur and "Food ideas to Help with Poor Appetite"
Sugar control may sometimes be Check your blood sugar regularly if you are
affected in diabetic patients. diabetic. Tell your doctor if your blood sugars
are not controlled.

Taste alteration may occur	Try the ideas in <i>"Food Ideas to Cope with</i>
	Taste and Smell Changes"*
Hair loss sometimes occurs and may	Use a gentle shampoo and soft brush.
begin within a few days or weeks of	Care should be taken with use of hair
treatment. Your hair may thin or you may	spray, bleaches, dyes, perms.
become totally bald. Your scalp may feel	Protect your scalp with a hat, scarf or wig in
tender. You may lose hair on your face	cold weather.
and body. Your hair will grow back once	Cover your head or apply sunblock on
your treatments are over and sometimes	sunny days.
between treatments. Colour and texture	Apply mineral oil to your scalp to reduce
may change.	itching.

<sup>\*</sup>Please ask your chemotherapy nurse, dietitian, or pharmacist for a copy

### INSTRUCTIONS FOR THE PATIENT

## What other drugs can interact with treatment?

- Other drugs such as some antibiotics given by vein (eg: tobramycin, vancomycin), furosemide (Lasix ®), phenytoin (Dilantin®), pyridoxine (Vitamin B6), 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.
- If you are admitted to hospital for intravenous antibiotics, be sure that the doctor treating you knows you are on cisplatin.

## Other important things to know:

- Cisplatin can cause changes in kidney function, but this is not frequent with the doses used in this type of treatment. It is important that you are well-hydrated before and after treatment.
- Sometimes, the nerve which allows you to hear can be affected by cisplatin. This could result in you experiencing "tinnitus" (ringing in the ears) or a change in your hearing. Report any of these problems to your doctor and/or nurse.
- 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 cisplatin and etoposide before you receive treatment of any form.

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#### 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 a **stroke** such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in an arm or leg.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain or shortness of breath.
- 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.
- Seizures or loss of consciousness.

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
<u> </u>

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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	604-877-6000
BC Cancer - Victoria	250-519-5500
www.bccancer.bc.ca/health-professionals/professional-reso	ources/cancer-drug-manual
Rev Aug 2018	· ·



To W	nom 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  ${\bf 1}$  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 <a href="https://www.bccancer.bc.ca">www.bccancer.bc.ca</a>.

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www.bccancer.bc.ca
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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 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 Kelowr 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 $8:30  \text{am} - 4:30  \text{pm}$ 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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