

For the Patient: Protocol LUAJNP

Other names: Adjuvant Treatment of Non-Small Cell Lung Cancer with Cisplatin and Vinorelbine

LU = LUng

AJ = AdJuvant

NP = Navelbine® (vinorelbine), cisPlatin

ABOUT THIS MEDICATION

What are these drugs used for?

- LUAJNP is an intravenous (through the vein) drug treatment for Non-Small Cell Lung Cancer. This treatment is given after you have had surgery to remove all visible cancer.
- Cisplatin and Vinorelbine are offered to people who have good kidney function and 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?

- Cisplatin is an anticancer drug that works by *preventing* the synthesis of DNA, RNA, and proteins that are needed for cancer cells to divide.
- Vinorelbine is an anticancer drug that is made from the leaves of the periwinkle plant. It works by interrupting the dividing and multiplying of cancer cells, and by encouraging the death of cancer cells.

INTENDED BENEFITS

- This treatment may reduce the chance of the lung cancer coming back.=

LUAJNP TREATMENT SUMMARY

How are these drugs given?

- Your treatment plan consists of 4 chemotherapy “cycles”. Each cycle lasts 3 weeks (21 days).
- For each cycle, you will have the two medications given to you intravenously (through the vein) on Day 1.
 - On Day 1, you will also be given extra fluids intravenously for one hour before cisplatin. This is to help flush out your kidneys.
 - Cisplatin is given first over one hour (60 minutes), then vinorelbine is given last over approximately 10 minutes.
- On Day 8 and Day 15 of each cycle, you will be given only vinorelbine over approximately 10 minutes.

Cycle 1:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Blood Test Prehydration, Cisplatin and Vinorelbine	No chemo	No chemo	No chemo	No chemo	No chemo	No chemo
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Blood Test Vinorelbine	No chemo	No chemo	No chemo	No chemo	No chemo	No chemo
Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21
Blood Test Vinorelbine	No chemo	No chemo	No chemo	No chemo	No chemo	No chemo

This 21-day cycle will repeat 3 more times

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 before Day 1, Day 8, and Day 15 of 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 how to manage them. *It is a good idea to bring someone with you to your first chemotherapy appointment.*
- The dose and timing of your chemotherapy may be changed based on your blood counts and/or other side effects. It is not uncommon for the Day 15 treatment to be skipped because of a low white blood cell count.
- 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 to each treatment. Your nurse will tell you when to take the anti-nausea medication. You may also need to take your anti-nausea medications at home after therapy. It is easier to prevent nausea than to treat it once it happens, so follow directions closely.

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 in the following chart(s) are particularly important for you to be aware of.

SERIOUS SIDE EFFECTS	How common is it?	MANAGEMENT
Your white blood cells may decrease 7-10 days 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.	Very common	To help prevent infection: <ul style="list-style-type: none"> • 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 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.	Common	To help prevent bleeding problems: <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. Avoid taking ASA (eg: ASPIRIN®) or Ibuprofen (eg: ADVIL®), <i>unless prescribed by your doctor.</i>
Allergic reactions may rarely occur. Signs of an allergic reaction are dizziness, confusion and wheezing/difficulty breathing. This reaction can occur immediately or several hours after receiving cisplatin, or after many doses of cisplatin.	Rare	Tell your nurse if this happens while you are receiving cisplatin. Go to your local Emergency Room immediately if this happens after you leave the clinic.
Cisplatin & Vinorelbine burn if they leak under the skin.	Very rare	Tell your nurse immediately if you feel burning, stinging, or any other change while the drugs are being given.

OTHER SIDE EFFECTS	How Common Is It?	MANAGEMENT
<p>Nausea and vomiting may occur after your treatment and may last for 24 hours.</p>	<p>Very Common</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. • Try the ideas in <i>“Food Choices to Control Nausea”</i>. <p>Be sure to let your doctor know if you have nausea or vomiting later than 24 hours after your treatment.</p>
<p>Constipation or diarrhea may occur.</p>	<p>Common</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 during Chemotherapy”</i>.
<p>Tiredness or lack of energy may occur.</p>	<p>Common</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 of Energy Savings: How People with Cancer can Handle Fatigue”</i>.

OTHER SIDE EFFECTS	How Common Is It?	MANAGEMENT
<p>Pain or tenderness may occur where the needle was placed within 1-2 days after treatment. This may extend all the way up the arm. Sometimes pain may occur where the cancer is located.</p>	Common	<ul style="list-style-type: none"> • Apply warm compresses or soak in warm water for 15-20 minutes several times a day. • For pain, take acetaminophen (eg: TYLENOL®). <p><i>See your doctor if the pain continues to bother you.</i></p>
<p>Numbness or tingling of the fingers or toes may occur. This will slowly return to normal once your treatments are over. This may take several months.</p>	Common	<ul style="list-style-type: none"> • 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.
<p>Hair loss sometimes occurs. If there is hair loss, your hair will grow back once you stop treatment. Colour and texture may change.</p>	Uncommon	<ul style="list-style-type: none"> • Use a gentle shampoo and soft brush. • Care should be taken with use of hair spray, bleaches, dyes and perms.
<p>Fever may occur shortly after treatment with vinorelbine. Fever should last <i>no more than 24 hours</i>.</p>	Uncommon	<ul style="list-style-type: none"> • Take acetaminophen (eg: TYLENOL®) every 3-4 hours. • Fever which occurs more than 48 hours after treatment may be the sign of an infection. See details above.
<p>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.</p>	Rare	<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.

INSTRUCTIONS FOR THE PATIENT

What other drugs can interact with LUAJNP?

- Other drugs such as aminoglycoside antibiotics (tobramycin, vancomycin), ethacrynic acid (EDECIN®), furosemide (LASIX®), phenytoin (DILANTIN®), or pyridoxine (Vitamin B6) may interact with LUAJNP. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests, your dose may need to be changed or the drug(s) may need to be held for a few days. Check with your doctor or pharmacist before you start taking any new drugs.

Other things to know:

- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of LUAJNP.
- LUAJNP may cause sterility in men and menopause in women. If you plan to have children, discuss this with your doctor before being treated.
- LUAJNP may damage sperm and may harm 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 are being treated with cisplatin and vinorelbine before you receive treatment of any form.

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

- 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 a **stroke** such as sudden onset of: severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin.
- Signs of an **allergic reaction** (rare) soon after a treatment including dizziness, fast heart beat, face swelling or breathing problems.
- 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 **heart problems** such as fast or uneven heartbeat.
- **Seizures** or **loss of consciousness**.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- **Muscle weakness.**
- Signs of **kidney problems** such as lower back or side pain, swelling of feet or lower legs.
- Uncontrolled **nausea** or **vomiting**.
- Signs of **anemia** such as unusual tiredness or weakness.

- Signs of **heart problems** such as shortness of breath or difficulty breathing, swelling of feet or lower legs.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- **Trouble in walking.**
- **Blood in your urine.**

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Easy bruising or bleeding.
- Uncontrolled nausea, vomiting, constipation or diarrhea.
- Severe jaw pain or headache.
- Redness, swelling, pain or sores where the needle was placed or along the arm.
- Redness, swelling, pain or sores on your lips, tongue, mouth or throat.
- Skin rash or itching.
- Numbness or tingling in feet or hands or painful leg cramps.

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** _____