

For the Patient: **LUAVCER**

Other Names: Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Ceritinib

LU = LUng
AV = AdVanced
CER = CERitinib

ABOUT THIS MEDICATION

What is this drug used for?

Ceritinib is a drug given to treat non-small cell lung cancer that is anaplastic lymphoma kinase (ALK) mutation-positive. It is a capsule which is taken by mouth.

How does this drug work?

Ceritinib works by interfering with certain enzymes called tyrosine kinases that are important in transmitting the chemical signals needed for essential processes like cell division and replication in cancer cells.

INTENDED BENEFITS

This treatment is being given 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.

LUAVCER TREATMENT SUMMARY

How is this drug given?

- Ceritinib is taken once a day, continuously, as long as you are benefiting from treatment and not having too many side effects.
- Ceritinib should be swallowed whole with a glass of water, and should be taken with food.

What will happen when I get the drug?

- A blood test is done within one month of starting treatment.
- A blood test is also done two weeks after starting treatment and each time you see your oncologist.
- The dose of your treatment may be changed based on your blood test results and/or other side effects.

SIDE EFFECTS AND MANAGEMENT:

- Your oncologist will review the risks of treatment and possible side effects with you before starting treatment.
- The pharmacist will review how to take the medication and possible side effects with you on the day you first pick up your medication.
- Unexpected and unlikely side effects can occur with any drug treatment. *The ones listed below are particularly important for you to be aware of.* Please refer to the patient information handout entitled “**For the Patient: Ceritinib**” for a complete list of possible side effects and their management.

| SERIOUS SIDE EFFECTS | MANAGEMENT |
|-----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Slow or abnormal heart rhythm (QT prolongation) rarely occurs</p> | <p>Minimize your risk of abnormal heart rhythm by:</p> <ul style="list-style-type: none"> • Always checking with your doctor and pharmacist about drug interactions when starting a new medication, herbal product or supplement. • Avoiding grapefruit and grapefruit juice and other similar fruits when taking ceritinib. <p>Tell your doctor immediately or get emergency help if your heart is beating irregularly or fast, or if you feel faint, lightheaded or dizzy.</p> |
| <p>Liver failure rarely occurs</p> | <ul style="list-style-type: none"> • Regular blood tests will be done throughout your treatment to monitor your liver function. • See your oncologist as soon as possible if you have signs of liver problems such as yellow eyes or skin, white or clay-colored stools. |
| <p>Lung problems rarely occur</p> | <p>Tell your doctor immediately or get emergency help if you have difficulty breathing, shortness of breath, cough or tightness in the chest.</p> |

| OTHER SIDE EFFECTS | MANAGEMENT |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Nausea and vomiting may occur.</p> | <p>You may be given a prescription for an anti-nausea drug(s) to take at home. It is easier to prevent nausea than to treat it once it has occurred, 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 Help Control Nausea</i> |

| OTHER SIDE EFFECTS | MANAGEMENT |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diarrhea commonly occurs | To help diarrhea: <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Ideas to Help Manage Diarrhea</i>. |
| Constipation may sometimes occur | To help with constipation: <ul style="list-style-type: none"> • Drink plenty of fluids. • Exercise if you can. • Try the ideas in <i>Suggestions for Dealing with Constipation</i>. |
| Normal 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 | To help prevent infection: <ul style="list-style-type: none"> • Wash your hands often and always after using the bathroom. • Avoid crowds and people who are sick. • Call your doctor immediately at the first sign of an infection such as a fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. |
| Eye problems , such as blurry or double vision, flashes of light and poor night vision may occur | <ul style="list-style-type: none"> • Use caution when driving or operating machinery, especially at night. • Tell your doctor at your next visit, especially if the changes don't go away or get worse. |
| Sugar control may sometimes be affected in diabetics | Check your blood sugar regularly if you are diabetic. |
| Skin rashes may sometimes occur | If very irritating, call your doctor. Otherwise, be sure to mention it at your next visit. |
| Numbness or tingling of the fingers or toes may sometimes occur | <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. |
| Tiredness and lack of energy may commonly occur | <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>. |

INSTRUCTIONS FOR THE PATIENT

What other drugs can interact with LUAVCER?

- Other drugs such as ketoconazole (NIZORAL®) and rifampin (RIFADIN®) may *interact* with ceritinib. 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 your treatment may need to be held for a few days.
- Check with your doctor or pharmacist before you start or stop taking any new prescription or non-prescription drugs, including natural health products.

Other important things to know:

- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with ceritinib.
- If you miss a dose of ceritinib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing times.
- If you vomit the dose of ceritinib, **do not** take a second dose. Call your doctor during office hours for advice as a medication to prevent nausea may be required for future doses.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of this treatment.
- Ceritinib may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while you are being treated with ceritinib and for 3 months after stopping treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Store ceritinib capsules out of the reach of children, at room temperature, away from heat, light and moisture.
- Tell all doctors or dentists you see that you are being treated with ceritinib before you receive any treatment from them.

If you experience symptoms or changes in your body that have not been described in “*For the Patient: Ceritinib*” but worry you, or if any symptoms are severe, contact: _____ at telephone number:
