

For the Patient: UTAAVLAR

Other Names: Treatment of Solid Tumours with Neurotrophic Tyrosine Receptor Kinase (NTRK) Fusion using Larotrectinib

U = UndesignatedTA = Tumour-AgnosticAV = AdVancedLAR = LARotrectinib

ABOUT THIS MEDICATION

What is this drug used for?

- Larotrectinib is a drug that targets a protein called Tyrosine Receptor Kinase (TRK) protein that is present in some cancers.
- Cancer that has a change in a gene called the Neurotrophic Tyrosine Receptor Kinase (NTRK) gene produces proteins called TRK fusion proteins. These proteins can cause cancer cells to grow.

How does this drug work?

 Larotrectinib (lar" oh trek' ti nib) targets the TRK fusion proteins and stops them from working. This helps slow down the cancer or stop the cancer from growing.

INTENDED BENEFITS

 This therapy is being given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay the onset of new symptoms.

TREATMENT SUMMARY

How is this drug given?

- Larotrectinib is provided as capsules that you will take by mouth.
- Larotrectinib is taken twice a day, continuously. This medication will be dispensed to you by a member of your cancer care team.
- Larotrectinib is taken every day, as long as you are benefiting from treatment and not having too many side effects, as determined by your cancer care team.

What will happen when I get my drug?

 Blood tests are done regularly during treatment. The dose and timing of your treatment may be changed based on your blood counts and/or other side effects.

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Developed: 1 Sep 2023 Revised:

INSTRUCTIONS

Tell your cancer care team if you have ever had an unusual or allergic reaction to larotrectinib before taking larotrectinib.

How should I store this drug?

Store larotrectinib capsules at room temperature, out of the reach of children, and away from heat, light, and moisture.

How should I take this drug?

- Larotrectinib is taken twice daily, at around the same times every day.
- You can take larotrectinib with food or on an empty stomach.
- Do not chew, open or crush larotrectinib capsules. Swallow whole with a full glass of water
- If you miss a dose of larotrectinib, take it as soon as you can if it is within 6 hours of the missed dose. If it is more than 6 hours since your missed dose, skip the missed dose and go back to your usual dosing times. Do NOT take a double dose to make up for the missed dose.
- If you vomit the dose of larotrectinib, do not take a second dose. Call your healthcare team during office hours for advice.

What other drugs or foods can interact with larotrectinib?

- Other drugs such as itraconazole (SPORANOX®) and rifampin (RIFADIN®) may interact with larotrectinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with larotrectinib
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of larotrectinib.

Note:

- Larotrectinib may affect fertility in women. If you plan to have children, discuss this with your doctor before being treated with larotrectinib.
- Larotrectinib may harm the baby if used during pregnancy. It is best to use birth control while being treated with larotrectinib and for at least one month after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for at least one week after the last dose.
- Tell your doctor, dentist, and other health professionals that you are being treated with larotrectinib before you receive any treatment from them.

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Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

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SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur. If you are vomiting and it is not controlled, you can quickly become dehydrated.	You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i> .* Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).
Skin rashes may sometimes occur.	If itching is very irritating, call your healthcare team. Otherwise, be sure to mention it at your next visit.
Fever may sometimes occur.	 Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. If you have fever (over 38°C or 100°F by an oral thermometer) plus another sign of infection, call your healthcare team immediately. Other signs of infection include chills, cough, or burning when you pass urine.
Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.	 If diarrhea is a problem: Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.* Tell your healthcare team if you have diarrhea for more than 24 hours.
Constipation may sometimes occur.	 Exercise if you can. Drink plenty of fluids. Try the ideas in Food Choices to Manage Constipation.*

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SIDE EFFECTS	MANAGEMENT
Your white blood cells may 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.	 To help prevent infection: Wash your hands often and always after using the bathroom. Avoid crowds and people who are sick. Stop taking larotrectinib and call your healthcare team <i>immediately</i> at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, cough, or burning when you pass urine.
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Nervous system problems such as confusion, changes in mood or memory, difficulty speaking, clumsiness, numbness or tingling of feet or hands, dizziness or tiredness can occur.	 Tell your healthcare team right away if you have signs of nervous system problems Do not drive a car or operate machinery if you are feeling tired. For tiredness, try the ideas in Fatigue/Tiredness – Patient Handout.*
Muscle or joint pain, or muscle weakness may sometimes occur.	You may 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 healthcare team if the pain interferes with your activity.
Swelling of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem:Elevate your feet when sitting.Avoid tight clothing.
You may sometimes have trouble sleeping.	 Tell your healthcare team if you continue to have trouble sleeping. This will return to normal when you stop taking larotrectinib.
Loss of appetite may sometimes occur.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
Hair loss does not occur with larotrectinib.	

*Please ask your nurse or pharmacist for a copy.

STOP TAKING LAROTRECTINIB AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- 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 an **infection** such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Seizures or fainting.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING **OFFICE HOURS) IF YOU HAVE:**

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of bladder problems such as changes in urination, painful burning sensation. presence of blood, or abdominal pain.

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING **CONTINUE OR BOTHER YOU:**

- Changes in taste.
- Abdominal pain.
- Numbness, tingling, or burning feeling in your hands or feet.
- Changes in weight or loss of appetite.
- Memory loss or confusion.
- Anxiety (nervousness or worry) or changes in mood that are not normal for you.
- Dizziness, loss of balance, trouble walking, or falls.
- Stuffy nose.

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:	

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