

## Larotrectinib (Vitrakvi)

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### About This Medicine

LAROTRECTINIB (LAR oh TREK ti nib) treats some types of cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Decrease in the number of white blood cells and red blood cells. This may raise your risk of infection and make you tired and weak.
- Decrease in a blood protein called albumin
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Tiredness
- Fever
- Changes in your liver function
- Decreased level of calcium in your blood
- Bone and muscle pain
- Feeling dizzy
- Cough

**Note:** *Each of the side effects above was reported in 20% or greater of people treated with larotrectinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your care team.*

### Warnings and Precautions

- Severe diarrhea which can be life-threatening
- Abnormal electrocardiogram (EKG/ECG) and changes in your heart's ability to pump blood properly



- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing
- Severe allergic skin reactions which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Changes in your liver function, which can cause liver failure and be life-threatening

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

## Important Information

This drug may impair your ability to drive or use machinery. Use caution and talk to your care team about any precautions you may need to take.

## How to Take Your Medicine

- **Capsules:** Swallow the medicine whole with water, with or without food. Do not crush or chew capsules.
- **Oral solution:** Please refer to the package insert for administration instructions.
- Equal doses of the oral solution and capsules can be substituted for each other.
- **Missed dose:** If you miss a dose, and it is less than 6 hours until your next dose, then skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than 6 hours until your next dose, take the missed dose. Do not take 2 doses at the same time or extra doses. Do not replace a vomited dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage: Capsules:** Store capsules in the original container at room temperature. Keep out of the reach of children and pets.
- **Storage: Oral solution:** Store oral solution in the original bottle in the refrigerator, between 36°F to 46°F (2°C to 8°C). Do not freeze. Opened bottles should be used within 31 days if 50 mL bottle and 90 days if 100 mL bottle. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.



- Be sure to include periods of rest between energy-draining activities.
- If you are dizzy, get up slowly after sitting or lying.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- Drink enough fluids to keep your urine pale yellow.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of larotrectinib in your body which could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with larotrectinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking larotrectinib as this may lower the levels of the drug in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and/or extreme weakness that interferes with your daily activities
- Agitation, confusion
- Feel irritable, nervous, or restless



- Feel abnormally well
- Lose interest in your daily activities that you used to enjoy and feeling this way every day, and/or you feel hopelessness
- Problems with memory and/or concentration
- Trouble falling or staying asleep
- Feeling dizzy or lightheaded
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Swelling of the hands, feet, or any other part of the body
- Pain that does not go away, or is not relieved by prescribed medicines
- Changes in your ability to move around or bone abnormalities
- Signs of low calcium: numbness or tingling around your mouth or in your hands and/or feet, muscle stiffness, twitching, spasms, or cramps

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 week after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 week after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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