VITRAKVI®: The first cancer treatment of its kind

VITRAKVI is an oral medicine that is not a chemotherapy.

Whether your doctor has already prescribed it or you're considering treatment with VITRAKVI (pronounced vi-trak-vee), this brochure can help answer some of your questions.

What is VITRAKVI?

VITRAKVI is a prescription medicine that is used to treat adults and children with solid tumors (cancer) that are caused by certain abnormal *NTRK** genes and have spread, or if surgery to remove their cancer is likely to cause severe complications, and there is no acceptable treatment option or the cancer grew or spread on other treatment.

Your healthcare provider will perform a test to make sure that VITRAKVI is right for you. It is not known if VITRAKVI is safe and effective in children younger than 28 days of age.

VITRAKVI was approved through a faster FDA review process based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long that response lasted. There are ongoing studies to confirm the benefit of VITRAKVI for this use.

Important Safety Information

VITRAKVI may cause **serious** side effects, including Central Nervous System (CNS) problems. VITRAKVI may cause dizziness, confusion, problems with concentration, attention, and memory, changes in your mood, and sleep problems.

**NTRK*, neurotrophic receptor tyrosine kinase.

Please see Important Safety Information throughout and click here for full Prescribing Information.

VITRAKVI® (larotrectinib) 25-mg/100-mg CAPSULES 20-mg/mL ORAL SOLUTION

HOW VITRAKVI® WORKS IN TRK FUSION CANCER

In some types of cancer, *NTRK* genes abnormally join with, or fuse to, other genes, which produces TRK* fusion proteins. These TRK fusion proteins can cause cancer cells to grow. When an *NTRK* gene fusion is found as the cause, this kind of cancer can also be called "TRK fusion cancer."

How does VITRAKVI work?

NTRK **gene joins with another gene**

Abnormal fusion causes TRK fusion proteins to be produced continually

TRK fusion proteins can signal cancer cells to grow

It is believed that VITRAKVI turns off the signal that causes TRK fusion cancer to grow†

VITRAKVI is an oral medicine that is not a chemotherapy

- VITRAKVI is the first medicine specifically designed to block TRK proteins
- VITRAKVI is thought to work by blocking these proteins and stopping cancer cells from growing, but the exact way VITRAKVI works is unknown
- VITRAKVI can work in a variety of tumor types as long as the tumor is caused by an *NTRK* gene fusion

The only way to find out if you have TRK fusion cancer is to test for it.

*FDA, Food and Drug Administration; TRK, tropomyosin receptor kinase.

†The way VITRAKVI acts in the body was determined from examining cells in a lab.

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Understanding TRK fusion cancer

TRK fusion cancer can occur in both adults and children. The location of a tumor can vary from person to person, but the cause is the same: an *NTRK* gene fusion. So having TRK fusion cancer doesn't change your original diagnosis, it just explains the cause of it.

What genomic testing can tell you about your cancer

Genomic testing may or may not have already been done on your cancer. It's important that you speak to your doctor about it. Genomic testing may reveal the cause of your cancer so your doctor has more information when deciding which treatment is right for you.

If your doctor has prescribed VITRAKVI®

Your doctor has tested your cancer and found that it is caused by a fusion of the *NTRK* gene

You've been matched with a treatment specifically for your TRK fusion cancer

If you and your doctor are considering potential treatments

You may want to learn whether a fusion of the *NTRK* gene is causing your cancer

Talk to your doctor about genomic testing to find out if VITRAKVI could be right for you

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- are caused by certain abnormal *NTRK* genes **and**
- have spread or if surgery to remove their cancer is likely to cause severe complications, **and**
- there is no acceptable treatment option **or** the cancer grew or spread on other treatment.

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Some questions you can ask your doctor about genomic testing:

- What are the different types of genomic tests?
- Which type of genomic test is best for me?
- How is genomic testing different than genetic testing?
- How can the results of a genomic test change my treatment course?

"I would tell other patients that, if you have the opportunity to have genomic testing done, go for it."
—Kayley, mother of Ashton, a TRK cancer patient

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EFFECTIVENESS OF VITRAKVI®

41 out of 55 patients had a response to treatment

A response* means that the cancer reduced in size and/or completely disappeared. Responses were analyzed across 3 clinical trials in 55 adults and children with TRK fusion cancer.

Larotrectinib demonstrated a centrally assessed ORR (primary study endpoint) of 75% (n=41/55); CR 25% (n=14/55) and PR 49% (27/55). It should be noted that 5% of the CR rate were pathological responses.†

25%† (14 patients) had a complete response, which means that their target tumors completely disappeared while on therapy, or underwent surgical resection to completely remove target tumors while on therapy

49% (27 patients) had a partial response, which means that their target tumors reduced in size by 30% or more

How long patients responded to treatment

- In patients who had their tumors disappear or shrink, responses lasted for a median of 32.9 months, with a range of **1.6+ to 50.6+**
- **63%** of patients had a response that lasted more than 12 months
- **49%** of patients had a response that lasted more than 24 months
- The median‡ time it took patients to respond to treatment was less than 2 months§

*A response is a sum of partial response and complete response. Partial response is defined as a reduction in size of target tumors by 30% or more and complete response is defined as complete disappearance of all target tumors, which means that their target tumors completely disappeared while on therapy or underwent surgical resection to completely remove target tumors while on therapy.

†5% were patients who had a partial response and were able to have surgery to be disease-free when the study data was analyzed.

‡The median is the middle number in a group of numbers.

§July 2019 data cutoff; 55 patients. The median time to response was 1.8 months (range 0.9 to 6.6).

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POSSIBLE SIDE EFFECTS

VITRAKVI may cause serious side effects including:

- **Central Nervous System (CNS) problems:** VITRAKVI may cause dizziness, confusion, problems with concentration, attention, and memory, changes in your mood, and sleep problems. Tell your healthcare provider if you develop any of these symptoms or they get worse. Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop VITRAKVI if you develop central nervous system symptoms with VITRAKVI.
- **Bone Fractures:** Bone fractures can happen with VITRAKVI. Tell your healthcare provider if you develop pain, changes in ability to move around, or bone abnormalities.
- **Liver problems:** Increased liver enzymes in blood tests are common in people who take VITRAKVI. Increased liver enzymes can sometimes lead to liver problems which can become serious. Your healthcare provider will do blood tests to check your liver function every 2 weeks during the first month of treatment with VITRAKVI, then monthly, as needed. Tell your healthcare provider right away if you develop symptoms of liver problems including: loss of appetite, nausea or vomiting, or pain on the upper right side of your stomach area. Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop VITRAKVI if you develop liver problems with VITRAKVI.

The most common side effects of VITRAKVI include:

- low red blood cell and white blood cell counts
- muscle and bone pain
- tiredness
- low levels of protein called albumin in the blood
- increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- cough
- constipation
- diarrhea
- dizziness
- low levels of calcium in the blood
- nausea
- vomiting
- fever
- stomach (abdomen) pain

VITRAKVI may affect fertility in females and may affect your ability to become pregnant if you are a woman. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects with VITRAKVI. Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at **1-800-FDA-1088**.

It is important to always talk with your healthcare provider about any side effects you have while taking VITRAKVI.

Talk to your healthcare provider to find out more about how VITRAKVI may help you.

VITRAKVI® (larotrectinib) 25-mg/100-mg CAPSULES 20-mg/mL ORAL SOLUTION

HOW TO TAKE VITRAKVI®

- Take VITRAKVI exactly as your healthcare provider tells you and report any side effects you may experience
- Your healthcare provider may stop treatment or change your dose of VITRAKVI if you have side effects. Do not change your dose or stop taking VITRAKVI unless your healthcare provider tells you
- If you have any questions, talk to your healthcare provider or pharmacist

VITRAKVI comes in capsules and a liquid formulation

100-mg and 25-mg capsules

20-mg/mL oral solution

Liquid Formulation available in:
- Two bottles, each containing 50 mL, strawberry flavor, or
- One 100-mL bottle

- Swallow VITRAKVI capsules whole. Do not chew or crush the capsules

If your healthcare provider prescribes VITRAKVI liquid formulation:
- Your healthcare provider will provide you with the VITRAKVI oral solution, oral syringes, and bottle adaptors or send you to a pharmacy that can provide you with VITRAKVI oral solution, oral syringes, and bottle adaptors
- Your healthcare provider should show you how to correctly measure and give a dose of VITRAKVI liquid formulation
- See the detailed Instructions for Use that come with VITRAKVI liquid formulation for information about the correct way to measure and give a dose of VITRAKVI liquid formulation

VITRAKVI is usually taken by mouth 2 times a day.
VITRAKVI can be taken with or without food.

- If you vomit after taking a dose of VITRAKVI, wait and take the next dose at your scheduled time
- If you miss a dose of VITRAKVI, take it as soon as you remember unless your next scheduled dose is due within 6 hours. Take the next dose at your regular time

Keep VITRAKVI liquid formulation in the refrigerator. Do not freeze

- Throw away any unused VITRAKVI liquid formulation
  - after 90 days of first opening a 100 mL bottle and
  - after 31 days of first opening a 50 mL bottle

- If you take too much VITRAKVI, call your healthcare provider

Please see Important Safety Information throughout and click here for full Prescribing Information.

TIPS TO HELP YOU STAY ON TRACK WITH YOUR TREATMENT

It is important to take VITRAKVI exactly as your healthcare provider tells you. Don't skip doses (unless your doctor has told you to) and try to take your medicine at the same time(s) every day. Here are a few tips that may help you stay on track with your treatment:

Keep VITRAKVI capsules in a place where you will see them and remember to take them (for instance, next to your bed)
- — Use a pillbox to keep track of each day's doses
- — Use a refrigerator magnet or calendar to help remember when to take VITRAKVI

Take your medicine as your doctor has directed to help keep the level of VITRAKVI in your body consistent.

Other tips for remembering to take VITRAKVI:

- Set a reminder on your phone or download a reminder app to alert you when it's time to take VITRAKVI
- Keep a small calendar or notepad near your medicine bottle so you can check off each time you take it
- Tap into your support system: Ask a friend or family member to remind you to take your medicine

Talk with your healthcare provider if you are having trouble taking your medicine as prescribed. He or she may be able to help.

Keep VITRAKVI and all medicines out of the reach of children.

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SUPPORT FOR TAKING VITRAKVI®

You're not in this alone

The Bayer Access Services (BAS) patient support program is a one-stop shop to help people who are taking VITRAKVI. BAS can:

- Find out if your health insurance plan covers VITRAKVI
- Provide resources to help you and your doctor assist with prior authorization if needed
- Connect you to a nurse or pharmacist who can answer treatment-related questions
- Let you know how much your co-pay will be
- Provide financial assistance for molecular diagnostic testing for eligible* patients with *NTRK* gene fusion
- Assist with applying for financial assistance by:
  - Enrolling you in the BAS $0 Co-pay Assistance Program for VITRAKVI.† You can also register by visiting VitrakviCopaySupport.com
  - Providing referrals to independent co-pay assistance foundations‡
  - Providing referrals to the Bayer US Patient Assistance Foundation

Access Services by Bayer™

To learn more about support through BAS, visit VITRAKVI.com or call 1-844-634-TRAK (8725).

*Eligible patients may be reimbursed up to $250 through BAS *NTRK* Gene Fusion Diagnostic Testing Co-pay Assistance Program. Eligible patients are defined as patients with a valid VITRAKVI® (larotrectinib) prescription for an FDA-approved indication who are residents of the United States, including the District of Columbia, Puerto Rico, Guam, or the US Virgin Islands. Patient cost-share obligations for office visits are not reimbursable under the Program. Payment of the reimbursement is subject to verification by Bayer in its sole discretion, as well as all the Terms and Conditions of the Program. Not valid for diagnostics covered by or submitted for reimbursement, in whole or part, under Medicare, Medicaid, TRICARE, and similar federal- or state-funded programs, or where otherwise prohibited by law. Bayer reserves the right to amend or terminate this program at any time without notice.

†Eligible patients may pay as little as $0 and save up to $25,000 per year. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, eg, co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, and may not participate if this program is prohibited by or conflicts with their private insurance policy, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in the Bayer US Patient Assistance Foundation are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of the BAS program at any time, including but not limited to this commercial co-pay assistance program.

‡TRAK Assist offers referrals to third-party assistance programs; eligibility criteria apply.

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CARING FOR SOMEONE WITH CANCER— AND CARING FOR YOURSELF TOO

Whether you're caring for a child, a spouse, or another family member, taking care of a person with cancer can be difficult. You may feel sad and overwhelmed. You may even have physical symptoms, such as trouble sleeping or tiredness. Taking care of yourself will also help you provide better support for your loved one.

Here are some suggestions for dealing with stress while caring for someone else:

- Eat healthy and exercise so you feel your best
- Do things you enjoy and get out of the house, for example, meet a friend for lunch or take a walk
- Ask for help from family and friends in caring for your loved one
- Seek out help from a support group or mental health professional

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ADDITIONAL RESOURCES

Helpful resources for patients and caregivers

American Cancer Society
1-800-227-2345
www.cancer.org

CANCER SUPPORT COMMUNITY
1-888-793-9355
www.cancersupportcommunity.org

CANCERcare
1-800-813-HOPE (4673)
www.cancercare.org

Staying organized

Between disease information, doctor's appointments, prescriptions, and medical bills, staying organized can feel like a full-time job. Here are a few ways to help you keep it all under control:

Try setting up a **personal health record (PHR)** on your computer, where you can input and manage all medical information in one place.
Visit **myPHR.com** to learn more

Carry a small **notebook and calendar** with you to jot down questions, side effects, appointments, etc

Save receipts, scans, lab reports, and other **paperwork** in a folder or binder, or scan them to save on your computer

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NOTES

CONSUMER BRIEF SUMMARY

About VITRAKVI® (vi-trak-vee)

VITRAKVI is a prescription medicine that is used to treat adults and children with solid tumors (cancer) that:

- are caused by certain abnormal *NTRK* genes **and**
- have spread or if surgery to remove their cancer is likely to cause severe complications, **and**
- there is no acceptable treatment option or the cancer grew or spread on other treatment.

Your healthcare provider will perform a test to make sure that VITRAKVI is right for you.

It is not known if VITRAKVI is safe and effective in children younger than 28 days of age.

VITRAKVI was approved through a faster FDA review process based on the percentage of patients whose tumor size shrank or disappeared after treatment and how long that response lasted. There are ongoing studies to confirm the benefit of VITRAKVI for this use.

Warnings about VITRAKVI

Central nervous system (CNS) problems: VITRAKVI may cause dizziness, confusion, problems with concentration, attention, and memory, changes in your mood, and sleep problems. Tell your healthcare provider if you develop any of these symptoms or they get worse. Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop VITRAKVI if you develop central nervous system symptoms with VITRAKVI.

Bone fractures: Bone fractures can happen with VITRAKVI. Tell your healthcare provider if you develop pain, changes in your ability to move around, or bone abnormalities.

Liver problems: Increased liver enzymes in blood tests are common in people who take VITRAKVI. Increased liver enzymes can sometimes lead to liver problems which can become serious. Your healthcare provider will do blood tests to check your liver function every 2 weeks during the first month of treatment with VITRAKVI, then monthly, as needed. Tell your healthcare provider right away if you develop symptoms of liver problems including: loss of appetite, nausea or vomiting, or pain on the upper right side of your stomach area. Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop VITRAKVI if you develop liver problems with VITRAKVI

What should I avoid while taking VITRAKVI?

- VITRAKVI can make you feel dizzy. Do not drive or operate machinery until you know how VITRAKVI affects you
- Avoid taking St. John's wort, eating grapefruit, or drinking grapefruit juice during treatment with VITRAKVI

Before starting VITRAKVI

Tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have nervous system (neurological) problems
- are pregnant or plan to become pregnant. VITRAKVI can harm your unborn baby. You should not become pregnant during treatment with VITRAKVI
  - If you are able to become pregnant, your healthcare provider may do a pregnancy test before you start treatment with VITRAKVI
  - Females who are able to become pregnant should use effective birth control (contraception) during treatment and for at least 1 week after the final dose of VITRAKVI. Talk to your healthcare provider about birth control methods that may be right for you
  - Males with female partners who are able to become pregnant should use effective birth control during treatment with VITRAKVI and for at least 1 week after the final dose of VITRAKVI
- are breastfeeding or plan to breastfeed. It is not known if VITRAKVI passes into your breast milk. Do not breastfeed during treatment and for 1 week after the final dose of VITRAKVI

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain other medicines may affect how VITRAKVI works and VITRAKVI may affect how other medicines work. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How to take VITRAKVI

- Take VITRAKVI exactly as your healthcare provider tells you
- Your healthcare provider may stop treatment or change your dose of VITRAKVI if you have side effects. Do not change your dose or stop taking VITRAKVI unless your healthcare provider tells you
- VITRAKVI comes in capsules and as an oral solution
- If your healthcare provider prescribes VITRAKVI oral solution:
  - Your healthcare provider will provide you with the VITRAKVI oral solution, oral syringes, and bottle adaptors or send you to a pharmacy that can provide you with VITRAKVI oral solution, oral syringes, and bottle adaptors
  - Your healthcare provider should show you how to correctly measure and give a dose of VITRAKVI oral solution
  - See the detailed Instructions for Use that comes with VITRAKVI oral solution for information about the correct way to measure and give a dose of VITRAKVI oral solution. If you have any questions, talk to your healthcare provider or pharmacist
- VITRAKVI is usually taken by mouth 2 times a day
- Swallow VITRAKVI capsules whole with water. Do not chew or crush the capsules
- Take VITRAKVI with or without food
- If you vomit after taking a dose of VITRAKVI, wait and take the next dose at your scheduled time
- If you miss a dose of VITRAKVI, take it as soon as you remember. If your next scheduled dose is due within 6 hours, skip the missed dose and take your next dose at your regular time

If you take too much VITRAKVI, call your healthcare provider or go to the nearest hospital emergency room right away.

What else should I know while taking VITRAKVI?

VITRAKVI may affect fertility in females and may affect your ability to become pregnant if you are a woman. Talk to your healthcare provider if this is a concern for you.

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Possible side effects of VITRAKVI

The most common side effects of VITRAKVI include:

- low red blood cell and white blood cell counts
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- tiredness
- low levels of protein called albumin in the blood
- increased levels of enzyme called alkaline phosphatase in the blood (test for liver or bone problems)
- cough
- constipation
- diarrhea
- dizziness
- low levels of calcium in the blood
- nausea
- vomiting
- fever
- stomach (abdomen) pain

These are not all the possible side effects with VITRAKVI. Call your healthcare provider for medical advice about side effects.

To get more information:

- Talk to your healthcare provider or pharmacist
- Visit **VITRAKVI.com** to obtain the FDA-approved product labeling
- Call Bayer at **1-888-842-2937**

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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