

What is VORANIGO?

VORANIGO (40 mg tablets) is a prescription medicine used to treat adults and children 12 years of age and older with certain types of brain tumors called astrocytoma or oligodendroglioma with an isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, following surgery. Your healthcare provider will perform a test to make sure that VORANIGO is right for you. It is not known if VORANIGO is safe and effective in children under 12 years of age.

What are the possible side effects of VORANIGO? VORANIGO may cause serious side effects, including:

• Liver problems. Changes in liver function blood tests may happen during treatment with VORANIGO and can be serious. Your healthcare provider will do blood tests to check your liver function before and during treatment with VORANIGO.

Please see additional Important Safety Information on pages 18 and 19 and accompanying <u>Full Prescribing</u> <u>Information</u>, including <u>Patient Information</u>.





IN THIS brochure

Use this brochure to further educate yourself on VORANIGO and the role it can play in your glioma treatment journey.

Find answers to many of your questions, gain a deeper understanding of gliomas, and discover what VORANIGO may mean for you.

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As you read about VORANIGO, you may encounter words you aren't familiar with. These specific terms are underlined at first mention throughout the brochure. Use the glossary on page 17 to discover the meaning of words and key terms.



UNDERSTANDING IDH-mutant glioma

What is IDH-MUTANT GLIOMA?

IDH-mutant glioma is a type of brain tumor that happens when a gene called IDH (isocitrate dehydrogenase) changes in a way that affects how brain cells grow. Detecting an IDH mutation in the tumor cells from your biopsy or surgery leads to the diagnosis of IDH-mutant astrocytoma or oligodendroglioma.

What you should know about IDH-mutant glioma



About 20% of gliomas in adults have IDH mutations. Another common type of glioma, called glioblastoma, has no IDH mutation.



The prognosis is usually better for astrocytoma and oligodendroglioma than for glioma without an IDH mutation.



IDH-mutant gliomas tend to continually grow even after surgery and should be regularly checked with an MRI.



Identifying mutations in your glioma helps you and your doctor decide the best treatment options for you.



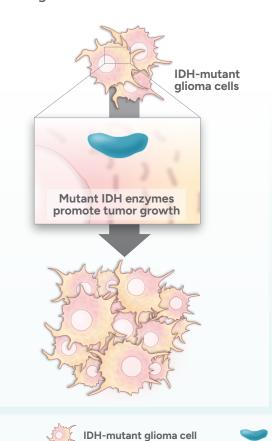
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VORANIGO® targets IDH-mutant glioma

VORANIGO is the only FDA-approved therapy **made specifically to treat** IDH-mutant astrocytoma or oligodendroglioma

VORANIGO works by targeting mutated IDH1 and IDH2 enzymes to help halt tumor progression. It is a targeted treatment that works differently than chemotherapy.

In glioma with an IDH mutation



VORANIGO goes inside glioma cells to target mutant IDH1/2 enzymes





Treatment with VORANIGO can begin immediately after surgery, including biopsy, without waiting for disease progression.



VORANIGO® CAN HELP halt progression*

*VORANIGO helped people live longer without their tumor growing.

VORANIGO was studied in a clinical trial called INDIGO.

This clinical trial compared people treated with once-daily VORANIGO to people treated with placebo (a sugar pill). The placebo group was used to help compare what results would be for people who chose to be on active observation with those who took VORANIGO after they were diagnosed with IDH-mutant glioma, and after surgery.

Progression-free survival (PFS)

VORANIGO lowered the chance of disease progression by

61%

compared with placebo^a

The median follow-up was 14 months with VORANIGO and 14.3 months with placebo.

IN THE INDIGO TRIAL,
VORANIGO GAVE PEOPLE LIVING WITH GRADE 2
IDH-MUTANT ASTROCYTOMA OR OLIGODENDROGLIOMA

more time

WITHOUT THEIR DISEASE PROGRESSING.

VORANIGO CAN HELP delay the need for additional treatment

Time to next intervention (TTNI)

24 months after starting VORANIGO,

8 OUT OF 10

people did not require additional treatment

such as chemotherapy, radiation, or another surgery^b

^b3 out of 10 people treated with placebo did not require an additional treatment.



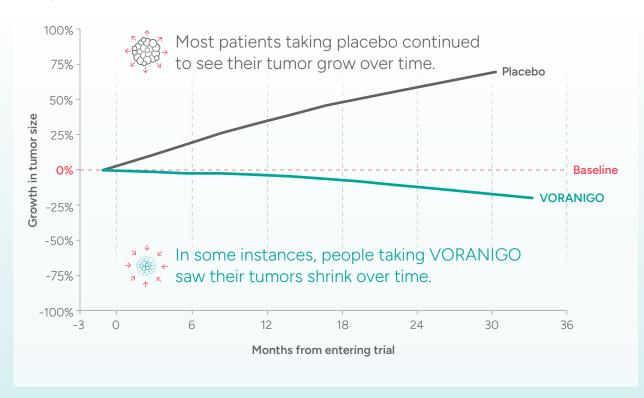
vorasidenib tablets

Changes in tumor size WITH VORANIGO® VS PLACEBO

An additional analysis from the INDIGO clinical trial studied how VORANIGO affected the growth of tumors over time compared to placebo. The results below show a change in tumor size for people in the trial.

Tumor growth rate was not the main goal of the study. Tumor growth rate is not a proven way to measure the treatment effects of VORANIGO, and it is unknown if these changes translate to measurable benefits for patients. It's important to keep this in mind when looking at these data.

Changes in tumor size from baseline







POSSIBLE SIDE EFFECTS with VORANIGO®

VORANIGO may cause serious side effects

The most common side effects of VORANIGO include:



Increased liver enzyme levels in the blood



Lack of energy, tiredness



Nausea



Muscle aches or stiffness



Headache



Seizures



Diarrhea



COVID-19

^aThe INDIGO trial began enrolling participants in 2020 and was conducted during the COVID-19 pandemic.

VORANIGO may cause serious side effects, including liver problems. Changes in liver function blood tests may occur during treatment with VORANIGO and can be serious.



Your healthcare provider will do blood tests to check your liver function before and during treatment with VORANIGO.

Tell your healthcare provider right away if you develop any of the following signs and symptoms of liver problems:



Yellowing of your skin or the white part of your eyes (jaundice)



Pain on the upper right side of your stomach area







Loss of appetite



WITH YOUR HEALTHCARE PROVIDER ABOUT ANY SIDE EFFECTS YOU MAY EXPERIENCE AND HOW TO MANAGE THEM.



WHAT YOU CAN EXPECT when taking VORANIGO®

VORANIGO is a once-daily pill

With VORANIGO, you can take control of your treatment schedule—choose a convenient, consistent time to take VORANIGO each day.

The standard dose of VORANIGO is one 40 mg pill taken by mouth.

 The dose for children 12 years and older who weigh 88 pounds or less (<40 kg) is 20 mg once daily by mouth

When taking VORANIGO, remember to:



Take VORANIGO exactly as your healthcare provider tells you, once a day, about the same time each day



Do not change your dose or stop taking VORANIGO without talking to your healthcare provider



Swallow VORANIGO pills whole with water. **Do not** split, crush, or chew the pills

Each bottle contains 30 tablets. Tablet not shown at actual size.

NDC 72694-784-40 Voranigo (vorasidenib) tablets 40 mg 40 mg 41 to fine, crush, or chew the shallets Applications to be the shall to be the shal

Questions about



MISSED DOSES, REPRODUCTION, OR ADDITIONAL CONSIDERATIONS WHILE TAKING VORANIGO?

Scan to visit Voranigo.com to help find answers.

Things to know about monitoring and treatment while taking VORANIGO

Before your doctor initiates VORANIGO, they will:

- Take a sample of your blood to check your blood count and liver enzyme levels
- If you are of childbearing age, make sure you are not pregnant



After you start VORANIGO, your doctor will take a sample of your blood about **every 2 weeks**. This will happen for the first 2 months of your treatment.



After that, your doctor will take another blood sample about once a month for the next 2 years while you are taking VORANIGO. Your doctor may decide to take blood samples more or less frequently depending on your results.

How is the length of treatment with VORANIGO determined?

Treatment with VORANIGO does not follow a predetermined number of months. VORANIGO can be taken as long as the disease does not progress or as long as the person can tolerate the medication. Over half of the people taking VORANIGO in the INDIGO clinical trial were on the treatment for over 1 year.

Reproductive health considerations:

Tell your healthcare provider if you are pregnant or plan to become pregnant, as VORANIGO may harm an unborn baby. It may affect fertility in females and males, which can impact the ability to have children.

You're encouraged to discuss family planning options with your healthcare provider, including referral to an oncofertility specialist.

Smoking any type of tobacco-based product may affect how well VORANIGO works.



If you currently smoke tobacco, inform your healthcare provider to discuss your options.



IS TARGETED TREATMENT WITH VORANIGO® RIGHT FOR YOU? *Talk to your doctor*

These questions can help guide a conversation between you How will I get my prescription for VORANIGO? and your healthcare team to determine if VORANIGO may be right for you. How do you determine for how long I will be taking VORANIGO? What kind of IDH mutation do I have? Can VORANIGO affect other medications I am taking? What kind of IDH-mutant glioma do I have? oligodendroglioma () astrocytoma What side effects should I watch for with VORANIGO? Is VORANIGO a possible treatment option for me right now? What should I do if I experience side effects? What impact could VORANIGO have on my glioma? How often will my follow-up visits be? If VORANIGO is the right treatment for me, how soon can I expect to start? MRIs: Liver function tests: How does VORANIGO work? Clinical visits: What are the benefits of a targeted treatment like VORANIGO? What else do I need to know when treating my glioma with VORANIGO?



DISCOVER ServierONE™



ServierONE understands the challenge of starting treatment for glioma, and offers prescription support and financial assistance.

Find personalized support and guidance to help you navigate access to VORANIGO®.

ServierONE provides:



Support with insurance coverage and reimbursement



Financial assistance to help you pay for VORANIGO tablets



Prescription fulfillment through our network of specialty pharmacies and distributors



Access to a one-on-one Patient Experience Manager



VORANIGO may be available for as little as \$0*

The \$0 Copay Program lowers the out-of-pocket cost of VORANIGO for eligible patients with commercial insurance to as little as \$0 per prescription.



Scan to learn more about the VORANIGO \$0 Copay program.

*For eligible patients with commercial insurance.

Email USPatientServices@servier.com

Call **1-800-813-5905** (Monday-Friday, 8 AM to 8 PM ET) to contact a Patient Services representative directly. For more details about the resources offered by ServierONE, visit **ServierONE.com**.

GLOSSARY

Astrocytoma: A type of glioma that forms in cells called astrocytes, which are found in the brain and spinal cord.

Biopsy: A procedure that collects and examines a suspected tumor tissue sample to diagnose the type and grade of a glioma or other kind of cancer.

Gene: Genes are pieces of DNA passed from parent to offspring, and most genes contain the information for making a specific protein.

Glioma: A group of tumors that form in glial cells in the brain and spinal cord.

Oligodendroglioma: A type of glioma that forms in cells called oligodendrocytes. These cells cover and protect nerve cells in the brain and spinal cord.

Placebo: A substance that does not contain any active medication.

Surgery: A procedure to reduce the size of, or remove as much of your tumor as possible, depending on location within your brain.

Targeted treatment: A treatment that targets proteins that control how cancer cells grow, divide, and spread.



IMPORTANT SAFETY INFORMATION

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- yellowing of your skin or the white part of your eyes (jaundice)
- dark tea-colored urine
- loss of appetite
- pain on the upper right side of your stomach area
- feeling very tired or weak

The most common side effects of VORANIGO include:

- increased liver enzyme levels in the blood
- lack of energy, tiredness
- headache
- COVID-19

- muscle aches or stiffness
- diarrhea
- nausea
- seizure

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with VORANIGO if you have certain side effects.

VORANIGO may affect fertility in females and males, which may affect the ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of VORANIGO.

Before taking VORANIGO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- · have kidney problems or are on dialysis
- smoke tobacco
- are pregnant or plan to become pregnant. VORANIGO can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with VORANIGO
- You should use effective nonhormonal birth control during treatment with VORANIGO and for 3 months after the last dose. VORANIGO may affect how hormonal contraceptives (birth control) work and cause them to not work well. Talk to your healthcare provider about birth control methods that may be right for you during treatment with VORANIGO
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with VORANIGO

Males with female partners who are able to become pregnant:

- You should use effective birth control during treatment with VORANIGO and for 3 months after the last dose
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she may be pregnant during your treatment with VORANIGO

Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if VORANIGO passes into breast milk. **Do not** breastfeed during treatment with VORANIGO and for 2 months after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VORANIGO may affect the way other medicines work, and other medicines may affect how VORANIGO works.







Scan to learn more about VORANIGO and discover additional resources at Voranigo.com.

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