Voranigo®
vorasidenib tablets

Treatment Management Guide

VORANIGO® is a once-daily oral treatment for Grade 2 m*IDH1/2* astrocytoma or oligodendroglioma[1]

INDICATION

VORANIGO (40 mg tablets) is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test, following surgery including biopsy, sub-total resection, or gross total resection.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity: VORANIGO can cause hepatic transaminase elevations, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis. Monitor liver laboratory tests (AST, ALT, GGT, total bilirubin, and alkaline phosphatase) prior to the start of VORANIGO, every 2 weeks during the first 2 months of treatment, then monthly for the first 2 years of treatment, and as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Reduce the dose, withhold, or permanently discontinue VORANIGO based on severity.

mIDH1/2, mutant isocitrate dehydrogenase-1 or mutant isocitrate dehydrogenase-2.

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

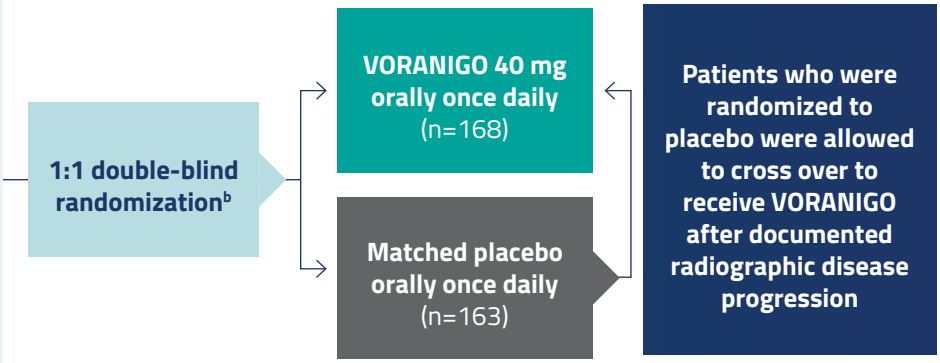
INDIGO trial design

The INDIGO trial evaluated the safety and efficacy of VORANIGO in patients with Grade 2 m*IDH1/2* astrocytoma or oligodendroglioma versus placebo[1]

A phase 3, randomized, multicenter, double-blind, placebo-controlled trial (N=331)[1,2]

Patients in the INDIGO trial:

- Were at least 12 years of age
- Had *IDH1*- or *IDH2*-mutant Grade 2 astrocytoma or oligodendroglioma[a]
- Had prior surgery for glioma
- Had measurable, non-enhancing disease
- Had not received prior anticancer therapy, including chemotherapy and radiotherapy



Treatment continued until radiographic disease progression or unacceptable toxicity.[1] Tumor assessments were performed every 12 weeks.

Major efficacy outcome: Progression-free survival (PFS)

Progression-free survival (PFS)
The time from randomization to the date of the first documented disease progression or death due to any cause.[2,c]

Data on additional endpoints including time to next intervention, tumor growth rate, and seizure activity are now available.
Speak to your local Servier representative to learn more.

[a] *IDH1* or *IDH2* mutation status was prospectively determined by the Life Technologies Corporation Oncomine Dx Target Test.[1]

[b] Randomization was stratified by local 1p/19q status (codeleted or not codeleted) and baseline tumor size (diameter ≥2 cm or <2 cm).[1]

[c] PFS was evaluated by a BIRC per modified RANO-LGG.[1] The RANO criteria for LGGs define progressive disease as either a radiographic disease response (a ≥25% increase in the sum of the products of perpendicular T2-weighted or T2-weighted fluid-attenuated inversion recovery), or the presence of a new lesion as a newly measurable or increased enhancement.[2]

[d] Number of events include progressive disease and death.[1]

BIRC, blinded independent review committee; HR, hazard ratio; RANO-LGG, Response Assessment in Neuro-Oncology for Low Grade Glioma.

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

PFS: primary and extended analysis

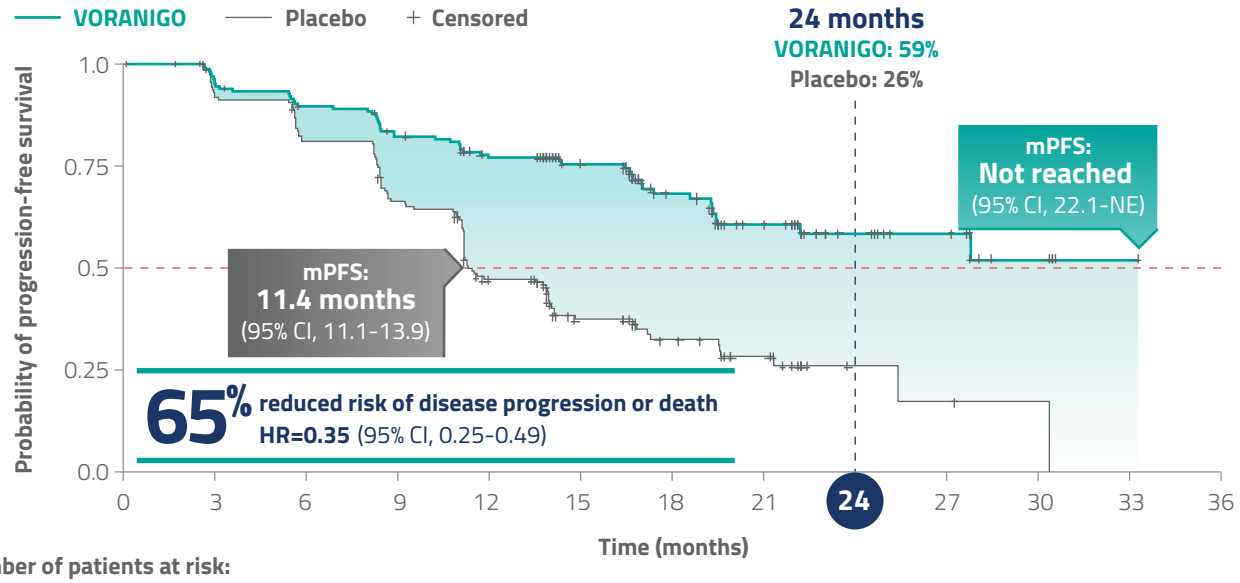
VORANIGO significantly extended PFS, giving patients with m*IDH* glioma more time without disease progression vs placebo[1]

Primary analysis: 61% reduced risk of disease progression or death with VORANIGO vs placebo (HR=0.39; 95% CI, 0.27-0.56; *P*<0.0001)[1]

Following the primary analysis data cutoff of September 6, 2022, the extended analysis includes 6 months of additional data to the date of unblinding on March 7, 2023.[2]

In the extended analysis, median PFS was not reached for VORANIGO vs 11.4 months with placebo[3]

Kaplan-Meier Curve for PFS per BIRC in the INDIGO trial: extended analysis



Number of patients at risk:

VORANIGO	168	157	147	133	117	85	57	35	17	12	5	1
Placebo	163	146	128	103	68	39	25	15	3	2	1	

PFS in patients with m*IDH* glioma

Efficacy parameter	Primary analysis[1]		Extended analysis[3]	
	VORANIGO (n=168)	**Placebo** (n=163)	**VORANIGO** (n=168)	**Placebo** (n=163)
Number of events,[d] n (%)	47 (28)	88 (54)	54 (32)	104 (64)
HR (95% CI)	0.39 (0.27-0.56)		0.35 (0.25-0.49)	

The extended analysis for PFS was not controlled for multiplicity.

Voranigo® vorasidenib tablets

Dosing and administration

VORANIGO is taken orally at the same time each day with or without food at home, at work, or wherever is best for your patients[1]

Recommended dosage:

Adult patients

- 40 mg orally once daily

Pediatric patients 12 years and older

- Patients weighing ≥40 kg: 40 mg orally once daily
- Patients weighing <40 kg: 20 mg orally once daily

Remind your patients who are taking VORANIGO of the following:

Swallow tablets whole with water with or without food.

Do not split, crush, or chew tablets.

Continue VORANIGO until disease progression or unacceptable toxicity.

- Take VORANIGO tablets at about the same time each day
  - If a dose is missed by less than 6 hours, take the missed dose as soon as possible
  - If a dose is missed by more than 6 hours, skip the missed dose and take the next dose at the scheduled time
- If vomiting occurs after taking a dose, do not take a replacement dose, and take the next dose at the scheduled time on the following day

Pediatric Use[1]

The safety and effectiveness of VORANIGO have been established in pediatric patients aged 12 years and older for the treatment of Grade 2 *IDH1*- or *IDH2*-mutant astrocytoma or oligodendroglioma. Use of VORANIGO for this indication in this age group is supported by evidence from an adequate and well-controlled study of VORANIGO in adult and pediatric patients with additional population pharmacokinetic data demonstrating that age had no clinically meaningful effect on the pharmacokinetics of VORANIGO. In addition, the course of *IDH1*- or *IDH2*-mutant astrocytoma or oligodendroglioma is sufficiently similar between adults and pediatric patients to allow extrapolation of pharmacokinetic data in adults to pediatric patients.

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

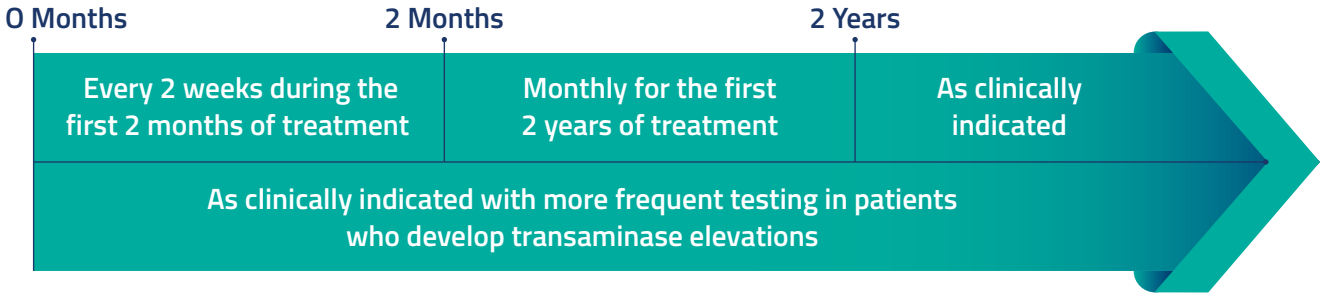
Monitoring and treatment considerations for VORANIGO[1]

Before initiating VORANIGO:

- Evaluate blood chemistry and liver laboratory tests
- Verify pregnancy status in females of reproductive potential

During treatment with VORANIGO:

- The VORANIGO USPI does not include recommendations for electrocardiogram monitoring before or during treatment
- Monitor liver laboratory tests (AST, ALT, GGT, total bilirubin, alkaline phosphatase) at the following intervals



Reduce the dose, withhold, or permanently discontinue VORANIGO based on severity.

Dosage interruption, reduction, or treatment discontinuation may be needed in patients who develop transaminase elevations

Considerations for your patients who are pregnant or planning to become pregnant

- Based on animal embryo-fetal toxicity studies, VORANIGO can cause fetal harm when administered to pregnant women
- Based on findings in animals, VORANIGO may impair fertility in females and males of reproductive potential. The effects on female and male fertility were not reversible in rats
- Advise females of reproductive potential to use effective nonhormonal contraception during treatment with VORANIGO and for 3 months after the last dose. VORANIGO can render some hormonal contraceptives ineffective
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with VORANIGO and for 3 months after the last dose
- Because of the potential for adverse reactions in breastfed children from VORANIGO, advise women not to breastfeed during treatment with VORANIGO and for 2 months after the last dose

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyl transferase.

Drug-drug interactions with VORANIGO

The following drugs may interact when co-administered with VORANIGO[1]

Review your patient's medication list before treatment with VORANIGO

Drug classification	Clinical impact	Prevention or management
Effect of other drugs on VORANIGO		
Strong and moderate CYP1A2 inhibitors	Concomitant use of VORANIGO with a strong or moderate CYP1A2 inhibitor may increase VORANIGO plasma concentrations, which may increase the risk of adverse reactions	▪ Avoid concomitant use of VORANIGO with strong and moderate CYP1A2 inhibitors ▪ If concomitant use of moderate CYP1A2 inhibitors cannot be avoided, monitor for increased adverse reactions and modify the dosage for adverse reactions as recommended
Moderate CYP1A2 inducers	Concomitant use of VORANIGO with moderate CYP1A2 inducers and smoking tobacco may decrease VORANIGO plasma concentrations, which may reduce the anti-tumor activity of VORANIGO	▪ Avoid concomitant use of VORANIGO with moderate CYP1A2 inducers and smoking tobacco
Effect of VORANIGO on other drugs		
Certain CYP3A substrates	Concomitant use of VORANIGO with CYP3A substrates may decrease plasma concentrations of CYP3A substrates	▪ Avoid concomitant use of VORANIGO with CYP3A substrates, where a minimal concentration change may lead to reduced therapeutic effect
Hormonal contraception	Concomitant use of VORANIGO may decrease the concentrations of hormonal contraceptives, which may lead to contraception failure and/or an increase in breakthrough bleeding	▪ If concomitant use cannot be avoided, use with nonhormonal contraception methods

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

Dose changes to VORANIGO in INDIGO

The median duration of exposure to VORANIGO for the primary safety analysis was 12.7 months (range: 1 to 30 months)[1,a]

Duration of exposure to VORANIGO	Number of patients
≥6 months	153 (92%)
≥1 year	89 (53%)

Dosage interruptions and discontinuations in patients treated with VORANIGO in the INDIGO trial[1,a]

Dosage interruptions

- Dosage interruptions of VORANIGO due to an adverse reaction occurred in 30% of patients
- Adverse reactions (ARs) which required dose interruption in ≥5% of patients included ALT increased (14%), COVID-19 (9%), and AST increased (6%)

Dose reductions

- Dose reductions of VORANIGO due to an adverse reaction occurred in 11% of patients
- ARs which required dose reduction in ≥5% of patients included ALT increased (8%)

Discontinuations

Permanent discontinuation of VORANIGO due to an AR occurred in 3.6% of patients

- ARs which resulted in permanent discontinuation of VORANIGO in ≥2% of patients included ALT increased (3%)

[a]The median duration of exposure and dose changes shown are from the INDIGO primary analysis.

Adverse reactions

The INDIGO trial assessed ARs of VORANIGO compared with placebo[1]

ARs reported in ≥5% of patients in the INDIGO trial

Adverse reaction[a]	All Grades (%)	Grades 3 or 4 (%)
General disorders	VORANIGO 40 mg daily (n=167) / Placebo (n=163)	
Fatigue[b]	37 / 36	0.6 / 1.2
Infections and infestations		
COVID-19	33 / 29	0 / 0
Nervous system disorders		
Seizure[c]	16 / 15	4.2 / 3.7
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain[d]	26 / 25	0 / 1.8
Gastrointestinal disorders		
Diarrhea[e]	25 / 17	0.6 / 0.6
Constipation	13 / 12	0 / 0
Abdominal pain[f]	13 / 12	0 / 0
Decreased appetite	9 / 3.7	0 / 0

- The safety results shown are based on the primary analysis.[1] The safety profile of VORANIGO for the extended analysis was consistent with the primary analysis[3]

[a]ARs are based on the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.

[b]Grouped term includes asthenia.

[c]Grouped term includes partial seizures, generalized tonic-clonic seizure, epilepsy, clonic convulsion, and simple partial seizures.

[d]Grouped term includes arthralgia, back pain, non-cardiac chest pain, pain in extremity, myalgia, neck pain, musculoskeletal chest pain, arthritis, and musculoskeletal stiffness.

[e]Grouped term includes feces soft and frequent bowel movements.

[f]Grouped term includes abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, and epigastric discomfort.

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

Select lab abnormalities

The INDIGO trial assessed lab abnormalities of VORANIGO compared with placebo[1]

Select laboratory abnormalities worsening from baseline occurring in ≥5% of patients

Parameter	All Grades[g] (%[h])	Grades[g] 3 or 4 (%[h])
Chemistry		
Increased ALT	59 25	10 0
Increased AST	46 20	4.8 0
Increased creatinine	11 7	0.6 0
Decreased calcium	10 7	0 0
Increased glucose[i]	10 4.3	0 0
Increased GGT	38 10	3 1.8
Decreased phosphate[j]	8 4.9	0.6 0
Increased potassium	23 20	0.6 0
Increased ALP	10 7	1.2 0.6
Hematology		
Increased hemoglobin	13 3.1	0 0
Decreased lymphocytes	11 8	1.8 0.6
Decreased leukocytes	13 12	0.6 0.6
Decreased neutrophils	14 12	2.4 1.8
Decreased platelets	12 4.3	0 0

VORANIGO 40 mg daily (n=167) Placebo (n=163)

Transaminase elevations resolved to Grade 1 or baseline levels after modifying or discontinuing treatment with VORANIGO[2]

[g]Based on NCI CTCAE v5.0.
[h]The denominator used to calculate percentages is N, the number of subjects in the Safety Analysis Set within each treatment group.
[i]Includes AR term hyperglycemia.
[j]Includes AR terms hypophosphatemia and blood phosphorus decreased.
ALP, alkaline phosphatase.

Most common ARs and dosage reductions due to ARs

The most common and severe ARs in patients who received VORANIGO[1]

- The most common (≥15%) ARs were fatigue (37%), COVID-19 (33%), musculoskeletal pain (26%), diarrhea (25%), and seizure (16%)
- Grade 3 or 4 (≥2%) laboratory abnormalities were ALT increased (10%), AST increased (4.8%), GGT increased (3%), and neutrophil decreased (2.4%)
- Serious ARs occurred in 7% of patients who received VORANIGO. The most common serious ARs occurring in ≥2% of patients who received VORANIGO includes seizure (3%)

Recommended dosage reductions of VORANIGO due to ARs[1]

Dosage reduction	Recommended dose and schedule
Adult patients and pediatric patients 12 years and older weighing ≥40 kg	
First	20 mg once daily
Second	10 mg once daily
Pediatric patients 12 years and older weighing <40 kg	
First	10 mg once daily
Permanently discontinue VORANIGO in patients unable to tolerate 10 mg once daily	

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

Adjustments to treatment due to ARs

Additional blood counts, including liver laboratory tests, and dosage modifications are recommended for increases in ALT, AST, and total bilirubin[1]

Recommended dosage modifications and management for adverse reactions

Adverse reaction	Severity[a]	Management and dosage modifications
Hepatotoxicity (Elevation of ALT or AST)	**Grade 1** ALT or AST increase >ULN to 3 x ULN *without* concurrent total bilirubin >2 x ULN	Continue VORANIGO at current dose Monitor liver laboratory tests weekly until recovery to <Grade 1
	Grade 2 ALT or AST >3 to 5 x ULN *without* concurrent total bilirubin >2 x ULN	**First occurrence:** Withhold VORANIGO until recovery to ≤Grade 1 or baseline ▪ Recovery in ≤28 days, resume VORANIGO at the same dose ▪ Recovery in >28 days, resume VORANIGO at reduced dose [See Table on page 10] **Recurrence:** Withhold VORANIGO until recovery to ≤Grade 1 or baseline, and resume VORANIGO at reduced dose [See Table on page 10]
	Grade 3 ALT or AST >5 to 20 x ULN *without* concurrent total bilirubin >2 x ULN	**First occurrence:** Withhold VORANIGO until recovery to ≤Grade 1 or baseline ▪ Recovery in ≤28 days, resume VORANIGO at reduced dose [see Table on page 10] ▪ If not recovered in ≤28 days, permanently discontinue VORANIGO **Recurrence:** Permanently discontinue VORANIGO
	Grade 2 or 3 ALT or AST >3 to 20 x ULN *with* concurrent total bilirubin >2 x ULN	**First occurrence:** Withhold VORANIGO until recovery to ≤Grade 1 or baseline ▪ Resume VORANIGO at reduced dose [See Table on page 10] **Recurrence:** Permanently discontinue VORANIGO
	Grade 4 Any ALT or AST >20 x ULN	Permanently discontinue VORANIGO
Other ARs	**Grade 3**	**First occurrence:** Withhold VORANIGO until recovery to ≤Grade 1 or baseline ▪ Resume VORANIGO at reduced dose [See Table on page 10] **Recurrence:** Permanently discontinue VORANIGO
	Grade 4	Permanently discontinue VORANIGO

[a]ARs graded by NCI CTCAE v5.0.

How VORANIGO is supplied, stored, and handled

How VORANIGO is supplied: 40 mg or 10 mg tablets supplied in 30-count bottles.[1]

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

VORANIGO is distributed through specialty pharmacies and distributors[1]

Dosage strength	40 mg/tablet	10 mg/tablet
NDC	10-digit code: **72694-728-40** 11-digit code: **72694-<u>0</u>728-40**	10-digit code: **72694-879-10** 11-digit code: **72694-<u>0</u>879-10**
Description	White to off-white, oblong film-coated tablet imprinted with "40" in black ink on one side and plain on the other side	White to off-white, round film-coated tablet imprinted with "10" in black ink on one side and plain on the other side
Cartons	Each carton contains one 30-count bottle of 40 mg tablets with desiccant canister(s) and child-resistant cap	Each carton contains one 30-count bottle of 10 mg tablets with desiccant canister(s) and child-resistant cap

The **bold, underlined zero** converts the 10-digit NDC to the 11-digit NDC. Some payers may require each NDC to be listed on the claim. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

Storage: Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C and 30 °C (59 °F to 86 °F).[1]

NDC, National Drug Code.

Please see additional Important Safety Information on page 15 and accompanying Full Prescribing Information.

Distribution network for VORANIGO

VORANIGO is supplied through specialty distributors and specialty pharmacies

Distribution network details

VORANIGO is available through specialty distributors for shipment directly to physician offices or hospital-based pharmacies.

McKesson Specialty Health

Multispecialty

1-855-477-9800
1-800-800-5673
mshcustomercare-mspl@mckesson.com
Msmc.mckesson.com

Oncology

1-800-482-6700
1-855-824-9489
oncologycustomersupport@mckesson.com
Msmc.mckesson.com

Cardinal Health Specialty Pharmaceutical Distribution (US)

Physician Office

1-877-453-3972
—
spdoncologyteam@cardinalhealth.com
specialtyonline.cardinalhealth.com

Hospitals/All Other

1-866-677-4844
1-614-652-7043
gmb-spd-csorderentry@cardinalhealth.com
orderexpress.cardinalhealth.com

Cardinal Health (Puerto Rico)

1-787-625-4100
1-787-625-4397
infopr@cardinalhealth.com
cardinalhealth.pr

ASD Healthcare

1-800-746-6273
1-800-547-9413
service@asdhealthcare.com
asdhealthcare.com

Oncology Supply

1-800-633-7555
1-800-248-8205
service@oncologysupply.com
oncologysupply.com

Network specialty pharmacies

VORANIGO ships directly from the specialty pharmacy to your patient's home or preferred location.

Biologics by McKesson

1-800-850-4306
1-800-823-4506
mycareteam@biologicsinc.com
biologics.mckesson.com

Onco360

1-877-662-6633
1-877-662-6355
CustomerCare@onco360.com
Onco360.com

ServierONE Patient Support Services

A program that helps with access and financial assistance

ServierONE Patient Support Services for VORANIGO includes:

- Support with insurance coverage and reimbursement
- Financial assistance to help patients pay for VORANIGO
- Prescription fulfillment through our network of specialty pharmacies and distributors
- Tools and resources to navigate the world of insurance

Contact a ServierONE representative if you have any questions via email at USPatientServices@servier.com or call 1-800-813-5905, Monday through Friday 8 AM to 8 PM ET

ServierONE connects your patients to financial assistance and coverage support programs

Commercial Copay Program

The ServierONE Commercial Copay Program may help lower out-of-pocket costs for patients prescribed VORANIGO.*

QuickStart Program

The ServierONE QuickStart Program may help provide patients access to VORANIGO before insurance coverage begins.*

Bridge Program

The ServierONE Bridge Program may help patients maintain access to VORANIGO during a lapse in insurance coverage.*

*Patient eligibility may vary.

Scan to visit ServierONE.com for full program details and information on how to enroll patients.

Important Safety Information

WARNINGS AND PRECAUTIONS

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Embryo-Fetal Toxicity: Based on findings from animal studies, VORANIGO can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective nonhormonal contraception during treatment with VORANIGO and for 3 months after the last dose, since VORANIGO can render some hormonal contraceptives ineffective. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with VORANIGO and for 3 months after the last dose.

ADVERSE REACTIONS

The most common (≥15%) adverse reactions included fatigue, headache, COVID-19, musculoskeletal pain, diarrhea, nausea, and seizure. Grade 3 or 4 (≥2%) laboratory abnormalities were ALT increased, AST increased, GGT increased, and neutrophils decreased.

DRUG INTERACTIONS

Avoid concomitant use of VORANIGO with strong and moderate CYP1A2 inhibitors. Avoid concomitant use with moderate CYP1A2 inducers and smoking tobacco. Avoid concomitant use with CYP3A substrates, where a minimal concentration change can reduce efficacy. If concomitant use of hormonal contraception cannot be avoided, use nonhormonal contraception methods.

LACTATION

Advise women not to breastfeed during VORANIGO treatment and for 2 months after the last dose.

IMPAIRED FERTILITY

VORANIGO may impair fertility of females and males of reproductive potential.

References: 1. Voranigo. Package insert. Servier Pharmaceuticals LLC; 2025. **2.** Mellinghoff IK, van den Bent MJ, Blumenthal DT, et al. Vorasidenib in IDH1- or IDH2-mutant low-grade glioma. *N Engl J Med.* 2023;389(7):589-601. doi:10.1056/NEJMoa2304194 **3.** Mellinghoff IK, van den Bent, MJ, Touat M, et al. A global, randomized, double-blinded, Phase 3 study of vorasidenib versus placebo in patients with adult-type diffuse glioma with an IDH1/2 mutation (INDIGO): UPDATED RESULTS. Presented at: Society for Neuro-Oncology Annual Meeting; November 21-24, 2024; Houston, TX. **4.** Ninatti G, Moresco RM, Sollini M. Molecular imaging of IDH-mutant gliomas in the new era of IDH inhibitors: preparing for future challenges. *Eur J Nucl Med Mol Imaging.* 2024;51(5):1421-1422. doi:10.1007/s00259-024-06591-3

VORANIGO is the first FDA-approved treatment in >20 years for m*IDH* glioma[1,4]

VORANIGO significantly extended PFS in the primary analysis (HR=0.39; *P*<0.0001), giving patients with m*IDH* glioma more time without disease progression vs placebo[1]

Permanent discontinuation of VORANIGO due to an AR occurred in 3.6% of patients. Adverse reactions which resulted in permanent discontinuation of VORANIGO in ≥2% of patients included ALT elevations (3%)[1]

VORANIGO is a once-daily oral treatment option. Regular and consistent monitoring of liver laboratory tests can help identify the need for dosage adjustments to VORANIGO

Scan to visit VoranigoHCP.com to access helpful resources about VORANIGO.

INDICATION

VORANIGO (40 mg tablets) is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation, as detected by an FDA-approved test, following surgery including biopsy, sub-total resection, or gross total resection.

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SERVIER

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