

DISTRIBUTION INFORMATION



FOTIVDA® (TIVOZANIB) IS AVAILABLE THROUGH A FOCUSED NETWORK OF SPECIALTY PHARMACIES AND SPECIALTY DISTRIBUTORS

Contact one of these authorized in-network specialty pharmacies or distributors for access to FOTIVDA.

Specialty Pharmacies (U.S.)	Phone	Fax	Website
Biologics	(800) 850-4306	(800) 823-4506	biologics.mckesson.com
Onco360	(877) 662-6633	(877) 662-6355	www.onco360.com

Specialty Distributors (U.S.)	Phone	Fax	Website
Cardinal Health Specialty Distribution	(855) 855-0708	(877) 274-9897	orderexpress.cardinalhealth.com
McKesson Plasma & Biologics	(877) 625-2566	(888) 752-7626	connect.mckesson.com
ASD Specialty Healthcare	(800) 746-6273	(800) 547-9413	www.asdhealthcare.com

FOTIVDA is also available for in-office dispensing by ordering through the listed specialty distributors.

Physician Dispensing Offices*	Phone	Fax	Website
Cardinal Health Specialty Distribution	(855) 855-0708	(877) 274-9897	specialtyonline.cardinalhealth.com
McKesson Specialty Health	(800) 482-6700	(800) 289-9285	mscs.mckesson.com
Oncology Supply	(800) 633-7555	(800) 248-8205	www.oncologysupply.com

*For Affiliated GPO members

For more information about access to FOTIVDA, visit www.FOTIVDA.com.

To prescribe FOTIVDA, either complete the AVEO ACE Program Enrollment Form and fax it to 1-888-920-2830 or send your patient's prescription to one of the authorized specialty pharmacies. Please do not fax the AVEO ACE Program Enrollment Form directly to the specialty pharmacy.

To enroll in the AVEO ACE Program, visit www.FOTIVDA.com to enroll online, or download and print the AVEO ACE Enrollment Form and fax to 1-888-920-2830. Once the Enrollment Form is submitted, an AVEO ACE Program Specialist will follow up with the patient or healthcare provider regarding next steps.

INDICATIONS

FOTIVDA is indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypertension and Hypertensive Crisis: Hypertension was reported in 45% of FOTIVDA-treated patients with 22% of the events \geq Grade 3. Hypertensive crises were reported in 0.8% of patients. Do not initiate FOTIVDA in patients with uncontrolled hypertension. Monitor for hypertension and treat as needed. Reduce the FOTIVDA dose for persistent hypertension not controlled by anti-hypertensive medications. Discontinue FOTIVDA for severe hypertension that cannot be controlled with anti-hypertensive therapy or for hypertensive crisis.

Cardiac Failure: Cardiac failures were reported in 1.6% of FOTIVDA-treated patients, with 1% of events reported as \geq Grade 3; 0.6% of events were fatal. Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA. Manage with dose interruption, dose reduction, or discontinuation.

(continued on next page)

Please see Important Safety Information throughout and full [Prescribing Information](#) for FOTIVDA® (tivozanib).

IMPORTANT SAFETY INFORMATION *(continued)*

WARNINGS AND PRECAUTIONS *(continued)*

Cardiac Ischemia and Arterial Thromboembolic Events: Cardiac ischemia in FOTIVDA-treated patients were reported in 3.2%; 0.4% of events were fatal. Arterial thromboembolic events were reported in 2.0% of FOTIVDA-treated patients, including death due to ischemic stroke (0.1%). Closely monitor patients who are at risk for, or who have a history of these events. Discontinue FOTIVDA in patients who develop severe arterial thromboembolic events, such as myocardial infarction and stroke.

Venous Thrombotic Events: Venous thromboembolic events were reported in 2.4% of FOTIVDA-treated patients, including 0.3% fatal events. Closely monitor patients who are at increased risk for these events. Discontinue FOTIVDA in patients who develop serious venous thromboembolic events.

Hemorrhagic Events: Hemorrhagic events were reported in 11% of FOTIVDA-treated patients; 0.2% of events were fatal. FOTIVDA should be used with caution in patients who are at risk for or who have a history of bleeding.

Proteinuria: Proteinuria was reported in 8% of FOTIVDA-treated patients, with 2% Grade 3. Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or interrupt treatment with FOTIVDA. Discontinue FOTIVDA in patients who develop nephrotic syndrome.

Thyroid Dysfunction: Thyroid dysfunction events were reported in 11% of FOTIVDA-treated patients, with 0.3% of events reported as \geq Grade 3. Monitor thyroid function before initiation and throughout treatment with FOTIVDA.

Wound Healing Complications: Withhold FOTIVDA for at least 24 days prior to elective surgery. Do not administer FOTIVDA for at least 2 weeks after major surgery and until adequate wound healing is observed. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): RPLS, a syndrome of subcortical vasogenic edema diagnosed by MRI, can occur with FOTIVDA. Evaluate for RPLS in patients presenting with seizures, headache, visual disturbances, confusion, or altered mental function. Discontinue FOTIVDA if signs or symptoms of RPLS occur.

Embryo-fetal Toxicity: FOTIVDA can cause fetal harm. Advise patients of the potential risk to a fetus, to avoid becoming pregnant and to use contraception during treatment and for one month after the last dose of FOTIVDA. Advise males with female partners of reproductive potential to use effective contraception during treatment and for one month after the last dose of FOTIVDA.

Allergic Reaction to Tartrazine: FOTIVDA 0.89 mg capsule contains FD&C Yellow No. 5 (tartrazine) as an imprint ink which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients.

ADVERSE REACTIONS

The most commonly reported (\geq 20%) adverse reactions were: fatigue/asthenia, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis. Serious adverse reactions reported in $>$ 2% of patients included bleeding (3.5%), venous thromboembolism (3.5%), arterial thromboembolism (2.9%), acute kidney injury (2.3%), and hepatobiliary disorders (2.3%).

DRUG INTERACTIONS

Strong CYP3A4 Inducers: Avoid coadministration of FOTIVDA with strong CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during FOTIVDA treatment and for at least 1 month after the last dose.

Renal Impairment: The recommended dosage for patients with end-stage renal disease has not been established.

Hepatic Impairment: Reduce the FOTIVDA dose for patients with moderate hepatic impairment. The recommended dosage in patients with severe hepatic impairment has not been established.

To report SUSPECTED ADVERSE REACTIONS, contact AVEO Pharmaceuticals, Inc. at 1-833-FOTIVDA (1-833-368-4832) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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