

For advanced kidney cancer

# FOTIVDA is the driving force to move you forward

An Information Brochure for People Considering or Taking FOTIVDA

## INDICATIONS

**FOTIVDA® (tivozanib) is a prescription medicine** used to treat adults with advanced kidney cancer (advanced renal cell carcinoma or RCC) that has been treated with 2 or more prior medicines and has come back or did not respond to treatment. It is not known if FOTIVDA is safe and effective in children.

**Please see the full Important Safety Information on pages 10-13 and [click here](#) for Patient Information in the full Prescribing Information for FOTIVDA® (tivozanib).**

 **FOTIVDA**<sup>®</sup>  
(tivozanib) capsules

## Keep moving forward

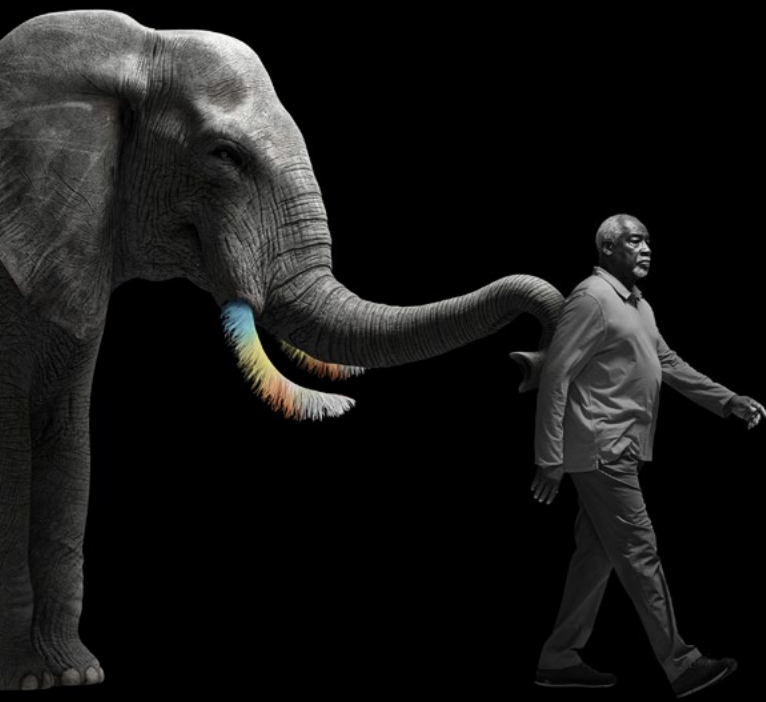
When advanced kidney cancer comes back, this is known as a *relapse*. And when your current medicine(s) stops working, this means that your cancer is *refractory*. If you are experiencing one of these, you are likely feeling concerned and wondering what's next.

You should know that you are not alone and that there are treatment options that can help you.

Your first step is to have an open and honest talk with your healthcare provider. That way, you can feel informed, reassured, and ready to take the next step in your treatment journey. It might help to prepare for your next visit by making a list of things you want to ask or talk about.

### Questions to ask your healthcare team:

- What are some of my choices for continuing treatment?
- Which treatment options are supported by meaningful clinical results?
- What are the different side effects with available treatment options?
- How will we decide if a treatment option is working?
- Is there a treatment option that can fit into my daily routine?
- Is there a program I can reach out to for support and resources during treatment?



**Get informed.**  
**Be engaged.**  
**Feel empowered.**

## What is FOTIVDA?



**FOTIVDA is the first and only approved treatment specifically for advanced kidney cancer where at least 2 medicines—which could include an immunotherapy—stopped working.**

Here are some of the most important things you need to know about FOTIVDA:

- ✓ Proven effectiveness and established safety profile
- ✓ Convenient oral dosing once daily, taken with or without food, for 21 days followed by a 7-day break
- ✓ Personalized support program with a wide variety of services to help you throughout your treatment journey

This handbook will go into detail about FOTIVDA. You can also learn more by visiting [www.FOTIVDA.com](http://www.FOTIVDA.com) or using the QR code shown here.



### SELECT IMPORTANT SAFETY INFORMATION

**FOTIVDA may cause serious side effects, including:**

**High blood pressure (hypertension).** High blood pressure may be severe, including a sudden, severe increase in your blood pressure (hypertensive crisis) that can lead to death. Your healthcare provider should check your blood pressure after 2 weeks and at least monthly and may prescribe medicine to treat high blood pressure. You should check your blood pressure regularly and tell your healthcare provider if you have increased blood pressure or experience confusion, headaches, dizziness, chest pain, or shortness of breath.

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# FOTIVDA helped people live significantly longer without their cancer growing or spreading

The effectiveness and safety of FOTIVDA was proven in the largest clinical study of people (350 people in total) with relapsed or refractory advanced kidney cancer where at least 2 medicines stopped working. These medicines included an immunotherapy and other treatments. During the study, 175 people were randomly chosen to take FOTIVDA and 175 were chosen to take sorafenib.

## The results:

**44%**

**increase in time without tumor growth or spread**

(5.6 months for FOTIVDA vs 3.9 months for sorafenib)

**28%** (49/175) experienced

**no cancer growth or spread for 1 year**

(compared with 11% [19/175] taking sorafenib)

## SELECT IMPORTANT SAFETY INFORMATION

**Heart failure.** Heart failure may be serious and sometimes lead to death. Your healthcare provider should check for symptoms of heart failure regularly, such as shortness of breath or swelling of your ankles.

**Heart attack and blood clots in your veins or arteries.** Blood clots may be serious and sometimes lead to death. Tell your healthcare provider or get emergency medical help right away if you have:

- new chest pain or pressure
- numbness or weakness on one side of your body
- pain in your arms, back, neck or jaw
- trouble talking
- shortness of breath
- sudden severe headache
- vision changes
- swelling in the arms or legs

# FOTIVDA showed tumor control

**Twice as many people who took FOTIVDA had their tumor(s) get smaller in size**

**18%** (32/175) experienced

**tumor shrinkage**

(compared with 8% [14/175] taking sorafenib)

**More people who took FOTIVDA had disease control**

**73%** (128/172) experienced

**disease control**

(compared with 65% [114/175] taking sorafenib)

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# More people stayed on FOTIVDA treatment

Almost **80%** were able to

**stay on treatment**

without stopping due to side effects  
(compared with 70% taking sorafenib)



In the study, 175 people took FOTIVDA and 175 people took sorafenib.

**76%** were able to

**take their full dose**

without reducing due to side effects  
(compared with 61% taking sorafenib)

Talk to your healthcare provider about FOTIVDA and find out if it's right for you.

## SELECT IMPORTANT SAFETY INFORMATION

**Protein in your urine.** Your healthcare provider should check your urine for protein before and during treatment.

**Thyroid gland problems.** Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment, and may prescribe medicine if you develop thyroid gland problems.

**Risk of wound-healing problems.** Wounds may not heal properly during treatment. Tell your healthcare provider if you plan to have surgery before starting or during treatment, including dental surgery.

- You should stop taking FOTIVDA at least 24 days before planned surgery.
- Your healthcare provider should tell you when you may start taking FOTIVDA again after surgery.

Please see the full Important Safety Information on pages 10-13 and [click here](#) for Patient Information in the full Prescribing Information for FOTIVDA® (tivozanib).



# Possible side effects of FOTIVDA

Possible serious side effects	
High blood pressure (hypertension)	Heart failure
Heart attack and blood clots in your veins or arteries	Bleeding problems
Protein in your urine	Thyroid gland problems
Risk of wound healing problems	Reversible Posterior Leukoencephalopathy Syndrome (RPLS)
Allergic reactions to tartrazine (FD&C Yellow No.5)	

## SELECT IMPORTANT SAFETY INFORMATION

**Bleeding problems.** Bleeding may be serious and sometimes lead to death. Report or get medical help right away if you have:

- unusual bleeding from the gums
- red or black stools (looks like tar)
- menstrual bleeding or vaginal bleeding that is heavier than normal
- bruises that happen without a known cause or get larger
- headaches, feeling dizzy or weak
- bleeding that is severe or you cannot control
- coughing up blood or blood clots
- pink or brown urine
- vomiting blood or your vomit looks like “coffee grounds”
- unexpected pain, swelling, or joint pain

Most common side effects	
Tiredness	Low levels of thyroid hormones
Diarrhea	Cough
Decreased appetite	Mouth sores
Nausea	Decreased levels of salt (sodium) and phosphate in the blood
Hoarseness	Increased levels of lipase in the blood (a blood test done to check your pancreas)

More information about side effects can be found on pages 10-13 of this handbook.

Remember that no 2 treatment experiences are the same—you may not get all of these side effects while taking FOTIVDA. Please call your healthcare provider right away if you experience any side effect.

Please see the full Important Safety Information on pages 10-13 and [click here for Patient Information in the full Prescribing Information for FOTIVDA® \(tivozanib\)](#).

# Indications and Important Safety Information

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It is not known if FOTIVDA is safe and effective in children.

**Possible serious side effects can occur with FOTIVDA. Call or see your healthcare provider right away if you develop:**

**High blood pressure (hypertension).** High blood pressure may be severe, including a sudden, severe increase in your blood pressure (hypertensive crisis) that can lead to death. Your healthcare provider should check your blood pressure after 2 weeks and at least monthly, and may prescribe medicine to treat high blood pressure. You should check your blood pressure regularly and tell your healthcare provider if you have increased blood pressure or experience confusion, headaches, dizziness, chest pain, or shortness of breath.

**Heart failure.** Heart failure may be serious and sometimes lead to death. Your healthcare provider should check for symptoms of heart failure regularly, such as shortness of breath or swelling of your ankles.

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- You should stop taking FOTIVDA at least 24 days before planned surgery.
- Your healthcare provider should tell you when you may start taking FOTIVDA again after surgery.

(continued on next page)

# Important Safety Information

(continued)

**Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** RPLS is a condition that can happen. Tell your healthcare provider right away if you have headaches, seizures, confusion, blindness or changes in vision, or difficulty thinking.

**Allergic reactions to tartrazine (FD&C Yellow No. 5).** FOTIVDA contains a dye called FD&C Yellow No. 5 (tartrazine) that may cause allergic-type reactions, including bronchial asthma, in certain people. This occurs most often in people who also are allergic to aspirin.

## The most common side effects of FOTIVDA include:

- tiredness
- diarrhea
- decreased appetite
- nausea
- hoarseness
- low levels of thyroid hormones
- cough
- mouth sores
- decreased blood levels of salt (sodium) and phosphate
- increased levels of lipase in the blood

Other side effects include vomiting and weakness or lack of energy. FOTIVDA may cause fertility problems in males and females, which may affect your ability to have a child.

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

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

**Before taking FOTIVDA, tell your healthcare provider about all your medical conditions,** including if you:

- have high blood pressure.
- have a history of heart failure.
- have a history of blood clots in your veins or arteries (types of blood vessels), including stroke, heart attack, or change in vision.
- have bleeding problems.
- have thyroid problems.
- have liver problems.
- have an unhealed wound.
- plan to have surgery or have had recent surgery, including dental surgery. You should stop taking FOTIVDA at least 24 days before planned surgery.
- are allergic to FD&C Yellow No.5 (tartrazine) or aspirin.
- are pregnant or plan to become pregnant. FOTIVDA can harm your unborn baby. If you are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment.
  - Use effective birth control (contraception) during treatment and for 1 month after your last dose.
  - Talk to your healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider right away if you become pregnant or think you might be pregnant.

**Tell your healthcare provider about all the medicine you take and any new medicine,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking FOTIVDA with certain other medicines may affect how FOTIVDA works.

**[Click here](#) for Patient Information in the full Prescribing Information for FOTIVDA® (tivozanib).**



# Once-daily FOTIVDA fits your lifestyle

## Convenient dosing at home or on the go



- One capsule, once daily
- With water, with or without food
- Every 21 days followed by a 7-day break

Remember to take FOTIVDA exactly as your healthcare provider tells you to take it.

### SELECT IMPORTANT SAFETY INFORMATION

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# People taking FOTIVDA can receive personalized and ongoing support

AVEO ACE is a comprehensive program dedicated to providing personalized support to you and your loved ones throughout the FOTIVDA treatment journey. Regardless of your insurance or financial circumstances, AVEO ACE Program Specialists connect you to the resources you need, with the goal of making access to FOTIVDA simple and streamlined.

<b>Insurance Coverage</b>	<ul style="list-style-type: none"> <li>• Work with your insurance company to conduct benefits investigation and provide coverage information to you and your healthcare professionals</li> <li>• Help you access FOTIVDA treatment if there are unexpected insurance coverage delays or interruptions</li> </ul>
<b>Financial Assistance</b>	<ul style="list-style-type: none"> <li>• Qualify for the AVEO ACE Co-pay Assistance Program and pay as little as \$0 for each prescription up to an annual limit of \$40,000 apply. Patients must have commercial insurance to qualify for this program</li> <li>• Get FOTIVDA at no cost if you are lacking adequate insurance coverage for FOTIVDA and meet certain financial criteria</li> <li>• Get connected with third-party foundations that may help lower your out-of-pocket costs for FOTIVDA</li> </ul>
<b>Ongoing Education and Support</b>	<p>When you join the AVEO ACE Patient Support Program, a specially trained oncology nurse specialist can be assigned as your single point of contact and can:</p> <ul style="list-style-type: none"> <li>• Provide general education on FOTIVDA treatment and what to expect while on treatment</li> <li>• Provide resources to help you and your loved ones understand and manage potential emotions experienced during the treatment journey</li> </ul>

AVEO ACE does not guarantee coverage or reimbursement. Coverage and reimbursement decisions are made by insurance companies following the receipt of claims. AVEO ACE is a service provided by AVEO Oncology. Representatives are not affiliated with your healthcare team. Medical questions should continue to be referred to your healthcare provider.

Learn more about the AVEO ACE program by visiting [www.FOTIVDA.com](http://www.FOTIVDA.com) or calling **1-833-FOTIVDA** (1-833-368-4832).





For advanced kidney cancer

# Ask your healthcare provider about FOTIVDA—the driving force that moves your treatment journey forward



**The only approved treatment specifically for people with relapsed or refractory advanced kidney cancer where at least 2 medicines—including an immunotherapy—have stopped working**

- Proven effectiveness and safety
- More people were able to stay on treatment
- Convenient dosing to fit your lifestyle
  - One capsule taken once daily by mouth, with or without food

**Get informed. Be engaged. Feel empowered.**

For more information about FOTIVDA, visit [www.FOTIVDA.com](http://www.FOTIVDA.com) or scan the QR code shown here.



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