

TREATMENT CYCLE						
<b>DAY 1</b>	<b>DAY 2</b>	<b>DAY 3</b>	<b>DAY 4</b>	<b>DAY 5</b>	<b>DAY 6</b>	<b>DAY 7</b>
Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>
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Dose: <input type="text"/>	Dose: <input type="text"/>	Dose: <input type="text"/>	Dose: <input type="text"/>	Dose: <input type="text"/>	Dose: <input type="text"/>	Dose: <input type="text"/>
<b>DAY 8</b>	<b>DAY 9</b>	<b>DAY 10</b>	<b>DAY 11</b>	<b>DAY 12</b>	<b>DAY 13</b>	<b>DAY 14</b>
Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>
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<b>DAY 15</b>	<b>DAY 16</b>	<b>DAY 17</b>	<b>DAY 18</b>	<b>DAY 19</b>	<b>DAY 20</b>	<b>DAY 21</b>
Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>
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TREATMENT BREAK Remember to call pharmacy for refill						
Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>

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<b>DAY 8</b>	<b>DAY 9</b>	<b>DAY 10</b>	<b>DAY 11</b>	<b>DAY 12</b>	<b>DAY 13</b>	<b>DAY 14</b>
Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>	Date: <input type="text"/>
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**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.

## IMPORTANT SAFETY INFORMATION

Before taking FOTIVDA, tell your healthcare provider about all your medical conditions including, if you have high blood pressure, a history of heart failure, a history of blood clots in your veins or arteries (including stroke, heart attack, or change in vision), bleeding problems, thyroid problems, liver problems, an unhealed wound, if you plan to have surgery or have had recent surgery, or are allergic to FD&C No. 5 (tartrazine) or aspirin.

Tell your healthcare provider if you are pregnant or planning to be. 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.
- Do not breastfeed during treatment and for 1 month after your last dose of FOTIVDA.

Tell your healthcare provider about all the medicine you take and any new medicine. Taking FOTIVDA with certain other medicines may affect how FOTIVDA works.

### **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. 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.
- **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
- **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

- **Protein in your urine.** Your healthcare provider should check your urine for protein before and during treatment.
- **Tear (perforation) in your stomach or intestines or an abnormal connection between two or more body parts (fistula).** Get medical help right away if you experience tenderness or pain in your stomach-area (abdomen) that is severe and does not go away.
- **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.
- **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.

**Common side effects** 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 the possible side effects of FOTIVDA.

**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](http://www.fda.gov/medwatch).**

**Please see the Patient Information in the full Prescribing Information for FOTIVDA® (tivozanib).**