

INLYTA® (axitinib)

About Advanced RCC

What is RCC?

Renal cell carcinoma (RCC) is the most common type of kidney cancer. It starts in the **kidney**, usually as 1 or more **tumors** in a single kidney. It's also possible for tumors to form in both kidneys at the same time.

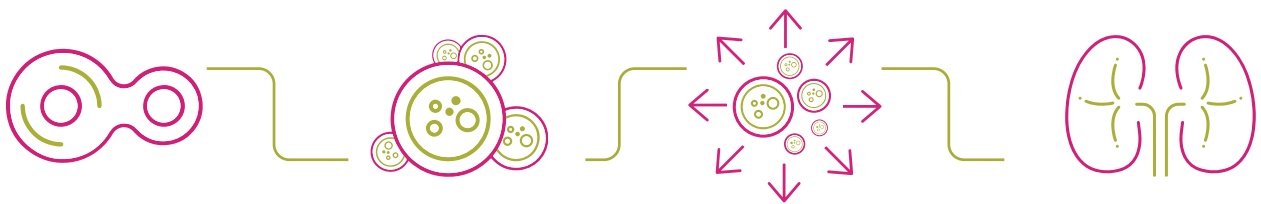
Advanced RCC refers to kidney cancer that has spread or cannot be removed by surgery.

Kidney = One of a pair of organs that removes waste products from the blood. In the process, they make urine to help carry waste products out of the body. One is on the left side of the abdomen. The other is on the right side.

Tumor = A mass of tumor cells.

How RCC Starts and Spreads

Cancer cells are abnormal versions of healthy cells. They grow and spread like normal cells but do so at abnormal rates with irregular shapes. Here's how:



1 A single RCC cell grows and divides to form 2 cells. This process repeats until a tumor is formed.

2 A tumor can be detected once enough cancer cells are made.


3 Some cancer cells may enter the bloodstream, spreading from the kidney to other parts of the body.

4 New tumors may spread to other organs. If this happens, the cancer is known as advanced or **metastatic**. But no matter where the cancer spreads, it will still be called advanced RCC because it started in the kidney.

Metastatic = Cancer that has spread from one part of the body to another through the lymphatic system or blood stream.

Stages of RCC

There are 4 stages of RCC. To determine the cancer's stage, doctors will measure the tumor size.

Stage 1	Tumor is found only in the kidney and is 7 centimeters (2.75 inches) or smaller	 Tennis ball (7 centimeters) image is not actual size
Stage 2	Tumor is found only in the kidney and is larger than 7 centimeters (2.75 inches)	
Stage 3	Cancer is found in the kidney and also beyond it, in areas such as a nearby lymph node , the tissue around the kidney, or the main blood vessels of the kidneys	
Stage 4	Cancer has spread beyond the kidney and may be found in multiple lymph nodes or other organs, such as the intestines, pancreas, or lungs	
Recurrent RCC	Recurrent RCC is cancer that has returned after it has been treated, coming back in the kidney and/or other parts of the body after the first treatment	

Lymph node = Located throughout the body, lymph nodes filter lymph fluid. They store special cells that can trap cancer cells or bacteria that are traveling through the body in the lymph.

Types of RCC Treatments

Below are some select RCC treatments. This is not a complete list and other treatment options may also be available.

Surgery

Surgery is an approach for patients with RCC that has not spread. It typically involves removing a kidney, or part of a kidney, in a procedure referred to as a nephrectomy.

Radiation therapy

Radiation is occasionally used in the management of RCC to ease cancer symptoms.

Tyrosine kinase inhibitor (TKI) therapy

Some cancer cells contain high levels of a type of enzyme called tyrosine kinase. When these enzymes are too active, they may cause cancer cells to grow. By blocking these enzymes, TKIs may slow the growth of cancer cells.

INLYTA® (axitinib) is a TKI that is used to treat kidney cancer that has spread or cannot be removed by surgery (advanced renal carcinoma or RCC) in combination with pembrolizumab as your first treatment, or alone when 1 prior drug treatment regimen for your RCC has not worked. It is not known if INLYTA is safe and effective in children.

Immuno-Oncology (IO) therapy

IO therapy refers to a kind of treatment that uses the body's immune system to attack abnormal cells and fight cancer. The immune system consists of immune checkpoints. IO therapies block some of these checkpoints, which may enable immune cells to start attacking the cancer cells. **Pembrolizumab is an IO therapy.**

Combination therapy

Combination therapy is when two or more different medicines are used to treat cancer. Since 2018, the FDA has approved the use of multiple therapies for treatment of advanced RCC. These include TKI and IO combinations, as well as IO and IO combinations.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

Before taking INLYTA® (axitinib), tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have thyroid problems
- have liver problems
- have a history of blood clots in your veins or arteries (types of blood vessels), including stroke, heart attack, or change in vision
- have any bleeding problems
- have a history of heart problems, including heart failure
- have an unhealed wound
- plan to have surgery or have had a recent surgery. You should stop taking INLYTA for at least 2 days before planned surgery

For females, tell your healthcare provider if you:

- are pregnant or plan to become pregnant. Taking INLYTA during pregnancy can harm your unborn baby. You should not become pregnant during treatment with INLYTA.
- are able to become pregnant. You should have a pregnancy test before you start treatment with INLYTA. Use effective birth control during treatment and for 1 week after your last dose of INLYTA. Talk to your healthcare provider about birth control methods that you can use to prevent pregnancy during this time.
- are breastfeeding or plan to breastfeed. It is not known if INLYTA passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of INLYTA.

For males with female partners who are able to become pregnant:

- use effective birth control during treatment and for 1 week after your last dose of INLYTA.
- if your female partner becomes pregnant during your treatment with INLYTA, tell your healthcare provider right away.

INLYTA® (axitinib) may cause **fertility problems** in males and females, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INLYTA and certain other medicines can affect each other causing serious side effects.

Talk with your healthcare provider before you start taking any new medicine. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Do not drink grapefruit juice or eat grapefruit. Grapefruit may increase the amount of INLYTA in your blood.

INLYTA may cause serious side effects, including:

- **High blood pressure (hypertension).** High blood pressure is common with INLYTA and may sometimes be severe. Your healthcare provider should check your blood pressure regularly during treatment with INLYTA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose, or stop your treatment with INLYTA
- **Blood clots in your veins or arteries.** INLYTA can cause blood clots which can be serious, and sometimes lead to death. Get emergency help and call your healthcare provider if you get any of the following symptoms:
 - chest pain or pressure
 - pain in your arms, back, neck or jaw
 - shortness of breath
 - numbness or weakness on one side of your body
 - trouble talking
 - headache
 - vision changes
- **Bleeding.** INLYTA can cause bleeding which can be serious, and sometimes lead to death. Call your healthcare provider right away or get medical help if you develop any of the following signs or symptoms:
 - unexpected bleeding or bleeding that lasts a long time, such as:
 - unusual bleeding from the gums
 - menstrual bleeding or vaginal bleeding that is heavier than normal
 - bleeding that is severe or you cannot control
 - pink or brown urine
 - red or black stools (looks like tar)
 - bruises that happen without a known cause or get larger
 - cough up blood or blood clots
 - vomit blood or your vomit looks like “coffee grounds”
 - unexpected pain, swelling, or joint pain
 - headaches, feeling dizzy or weak

- **Heart failure.** Your healthcare provider should check you for signs or symptoms of heart failure regularly during treatment with INLYTA® (axitinib). Heart failure can be serious and can sometimes lead to death. Tell your healthcare provider if you have any of the following symptoms during your treatment with INLYTA:
 - tiredness
 - swelling of your stomach-area (abdomen), legs or ankles
 - shortness of breath
 - protruding neck veins
- **Tear in your stomach or intestinal wall (perforation).** A tear in your stomach or intestinal wall can be serious and can sometimes lead to death. Get medical help right away if you get the following symptoms:
 - severe stomach-area (abdominal) pain or stomach-area pain that does not go away
 - vomit blood
 - red or black stools
- **Thyroid gland problems.** Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment with INLYTA. Tell your healthcare provider if you have any of the following symptoms during your treatment with INLYTA:
 - tiredness that worsens or that does not go away
 - feeling hot or cold
 - your voice deepens
 - weight gain or weight loss
 - hair loss
 - muscle cramps and aches
- **Risk of wound healing problems.** Wounds may not heal properly during INLYTA treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with INLYTA.
 - You should stop taking INLYTA at least 2 days before planned surgery
 - Your healthcare provider should tell you when you may start taking INLYTA again after surgery
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen during treatment with INLYTA. Call your healthcare provider right away if you get:
 - headache
 - seizures
 - weakness
 - confusion
 - high blood pressure
 - blindness or change in vision
 - problems thinking
- **Protein in your urine.** Your healthcare provider should check your urine for protein before and during your treatment with INLYTA. If you develop protein in your urine, your healthcare provider may decrease your dose of INLYTA or stop your treatment.

- **Liver problems.** Your healthcare provider will do blood tests before and during your treatment with INLYTA® (axitinib). Your healthcare provider may delay or stop your treatment with INLYTA if you develop severe liver problems.

Tell your healthcare provider right way if you have any of the following symptoms:

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

The most common side effects of INLYTA with pembrolizumab include:

- diarrhea
- feeling tired or weak
- high blood pressure
- liver problems
- low levels of thyroid hormone
- decreased appetite
- rash, redness, itching or peeling of your skin on your hands and feet
- nausea
- mouth sores or swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- hoarseness
- rash
- cough
- constipation

Important information: If your healthcare provider prescribes INLYTA for you to be taken with pembrolizumab, also read the [Medication Guide for pembrolizumab.](#)

The most common side effects of INLYTA when used alone include:

- diarrhea
- high blood pressure
- feeling tired or weak
- decreased appetite
- nausea
- hoarseness
- rash, redness, itching or peeling of your skin on your hands and feet
- decreased weight
- vomiting
- constipation

These are not all of the possible side effects of INLYTA. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call **1-800-FDA-1088**.

INDICATIONS

INLYTA® (axitinib) is a prescription medicine used to treat kidney cancer that has spread or cannot be removed by surgery (advanced renal cell carcinoma or RCC):

- in combination with pembrolizumab as your first treatment
- alone when 1 prior drug treatment regimen for your RCC has not worked

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

Please see full [Prescribing Information](#) and [Patient Information](#) for INLYTA.