

Inlyta[®] (axitinib) for Kidney Cancer

Inlyta is a medication used to treat advanced kidney cancer in adults when one prior drug treatment for this disease has not worked

Dosage: 5mg taken twice a day

How supplied: 5mg and 1mg tablets

Storage: Room temperature

Route of Administration: Inlyta is a tablet(s) taken by mouth

Schedule: twice a day, approximately 12 hours apart

How should I take Inlyta?

- Take it exactly the way your healthcare provider tells you
- Your doctor may change your dose if needed
- Take it with or without food
- Take it 2 times a day approximately 12 hours apart
- Swallow the tablets whole with a glass of water
- Your doctor should check your blood pressure regularly during treatment
- If you vomit or miss a dose, take your next dose at your regular time. Do not take two doses at the same time.
- If you think you have taken an extra dose of this medication, call your healthcare provider right away or go to the nearest hospital emergency room right away.

Dietary restrictions: Can be taken with or without food

- You should not drink grapefruit juice or eat grapefruit during your treatment with Inlyta. That may increase the amount of Inlyta in your body to a harmful level.

I should tell my healthcare provider if I:

- 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 an unhealed wound
- plan to have surgery. You should stop taking Inlyta at least 24 hours before planned surgery
- have any other medical conditions

For females, tell your doctor if you:

- are pregnant or plan to become pregnant. Taking Inlyta during pregnancy may cause the death of an unborn baby or birth defects. You should not become pregnant while you are taking Inlyta. Talk to your doctor if you are pregnant or plan to become pregnant.
- are able to become pregnant. You should use effective birth control during your treatment with Inlyta. Talk to your doctor about birth control methods to prevent pregnancy while you are taking Inlyta.
- are breast-feeding or plan to breast-feed. It is not known if Inlyta passes into your breast milk. You and your doctor should decide if you will take Inlyta or breast-feed. You should not do both.

For males:

- use effective birth control during your treatment with Inlyta. Talk to your doctor about birth control methods.
- if your female partner becomes pregnant while you are taking Inlyta, tell your doctor right away.

Tell your healthcare provider at each visit about all the medications you take including prescription and non-prescription medicine, vitamins, and herbal supplements. Inlyta may affect the way other medicines work and other medicines may affect how Inlyta works.

Especially tell your doctor if you take:

- dexamethasone (Decadron)
- bosentan (Tracleer)
- modafinil (Provigil)
- St. John's Wort (*Hypericum perforatum*)
- Medicine for:
 - asthma
 - tuberculosis
 - seizures
 - bacterial infections
 - fungal infections
 - depression
 - HIV or AIDS

Ask your doctor or pharmacist if you are not sure if your medicine is one listed above. If you are taking any medicines for the conditions listed above, your doctor might need to prescribe a different medicine or your dose of Inlyta may need to be changed. Talk with your doctor before you start taking any new medicine.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of Inlyta?

Inlyta may cause serious side effects including:

- High blood pressure (hypertension). Your doctor should check your blood pressure regularly during treatment with Inlyta. If you develop blood pressure problems, your doctor may prescribe medicine to treat your high blood pressure, lower your dose, or stop your treatment with Inlyta.
- Thyroid gland problems. Your doctor should do blood tests to check your thyroid gland function before and during your treatment with Inlyta. Tell your doctor 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
- Problems with blood clots in your veins or arteries. Get emergency help and call your doctor 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 doctor or get medical help if you develop any bleeding, including:
 - unusual bleeding from the gums
 - menstrual bleeding that is heavier than normal
 - vaginal bleeding
 - bleeding that is severe or you cannot control
 - pink or brown urine
 - red or black stools (looks like the color of tar)
 - bruises that happen without a known cause or get larger
 - coughing 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
- Tear in your stomach or intestinal wall (perforation). Get medical help right away if you get the following symptoms:
 - stomach or abdominal pain that does not go away
 - vomiting blood
 - red or black stools
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS). A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen while taking Inlyta. Call your doctor right away if you get:
 - headache
 - blindness or change in vision
 - seizures
 - weakness
 - confusion
 - high blood pressure
 - problems thinking
- Increased protein in your urine. Your doctor should check your urine for protein before and during your treatment with Inlyta. If you develop protein in your urine, your doctor may decrease your dose of Inlyta or stop your treatment.
- Change in liver function. Your doctor should do blood tests before and during your treatment with Inlyta to check your liver function.

Common Side effects of Inlyta include:

- diarrhea
- high blood pressure
- tiredness or feeling 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. Tell your healthcare provider if you have any side effects that bother you or that do not go away. Call your doctor for medical advice about side effects. For more information, ask your healthcare provider or pharmacist.

General information about Inlyta: Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use Inlyta for a condition for which it was not prescribed. Do not give Inlyta to other people, even if they have the same symptoms you have. It may harm them.

This patient information sheet summarizes the most important information about Inlyta. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Inlyta that is written for healthcare professionals.

Patient Assistance Program: FIRST RESOURCE is a reimbursement program from Pfizer. To enroll, speak to your healthcare provider, call 1-877-744-5675, or go to www.inlyta.com (click on "Access Inlyta")

Resources: Pfizer 1-877-744-5675
www.inlyta.com

Adapted from the Inlyta (Axitinib) package insert. Pfizer, August 2014

KCA disclaimer statement: you should rely primarily upon your doctor for medical information.

www.kidneycancer.org