

PATIENT INFORMATION

INLYTA[®] (axitinib) tablets

Read this Patient Information before you start taking INLYTA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is INLYTA?

INLYTA is a prescription medicine used to treat advanced kidney cancer (advanced renal cell carcinoma or RCC) when one prior drug treatment for this disease has not worked.

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

What should I tell my doctor before taking INLYTA?

Before you take INLYTA, tell your doctor 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 failure
- 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 can cause the death of an unborn baby or birth defects. You should not become pregnant while 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 breastfeeding or plan to breastfeed. It is not known if INLYTA passes into your breast milk. You and your doctor should decide if you will take INLYTA or breastfeed. 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 doctor 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.

Especially tell your doctor if you take:

- dexamethasone
- bosentan
- modafinil
- 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.

How should I take INLYTA?

- Take INLYTA exactly as prescribed by your doctor.
- Your doctor may change your dose if needed.
- INLYTA can be taken with or without food.
- Take INLYTA 2 times a day about 12 hours apart.
- Swallow INLYTA tablets whole with a glass of water.
- Your doctor should check your blood pressure regularly during treatment with INLYTA.
- If you vomit or miss a dose of INLYTA, take your next dose at your regular time. Do not take two doses at the same time.
- If you take too much INLYTA, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking INLYTA?

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

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.
- **Problem with 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 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 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 doctor should check for signs or symptoms of heart failure regularly during treatment with INLYTA. Heart failure can be serious and can sometimes lead to death. Tell your doctor 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 (abdominal) pain or stomach pain that does not go away
 - vomit blood
 - red or black stools
- **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
- **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
 - seizures
 - weakness
 - confusion
 - high blood pressure
 - blindness or change in vision
 - 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.

The most common side effects of INLYTA include:

- diarrhea (frequent or loose bowel movements)
- 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

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of INLYTA. For more information, ask your doctor or pharmacist.

How should I store INLYTA?

- Store INLYTA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep INLYTA and all medicines out of the reach of children.

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 leaflet 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 health professionals.

What are the ingredients in INLYTA?

Active ingredient: axitinib.

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, and Opadry® II red 32K15441. The Opadry II red 32K15441 film coating contains: lactose monohydrate, HPMC 2910/Hypromellose 15cP, titanium dioxide, triacetin (glycerol triacetate), and red iron oxide.

August 2014
Hong Kong