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Axitinib

pronounced as (ax i' ti nib)

Why is this medication prescribed?

Axitinib is used alone to treat advanced renal cell carcinoma (RCC, a type of cancer that begins in the cells of the kidneys) in people who have not been treated successfully with another medication. Axitinib is used in combination with avelumab (Bavencio) or pembrolizumab (Keytruda) to treat advanced renal cell carcinoma. Axitinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps slow or stop the spread of cancer cells.

How should this medicine be used?

Axitinib comes as a tablet to take by mouth. It is usually taken with or without food two times a day. Take axitinib at around the same times every day, about 12 hours apart. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take axitinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole with a glass of water; do not split, chew, or crush them.

If you vomit after taking axitinib, do not take another dose. Continue your regular dosing schedule.

Your doctor may start you on a low dose of axitinib and gradually increase your dose, not more than once every 2 weeks. This depends on how well the medication works for you and any side effects you might experience. Talk to your doctor about how you are feeling during your treatment. Continue to take axitinib even if you feel well. Do not stop taking axitinib without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking axitinib,

- tell your doctor and pharmacist if you are allergic to axitinib, any other medications, or any of the ingredients in axitinib tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: bosentan (Tracleer); carbamazepine (Carbatrol, Epitol, Tegretol); clarithromycin (Biaxin, in Prevpac); itraconazole (Sporanox); ketoconazole (Nizoral); medications to treat HIV/AIDs including atazanavir (Reyataz), efavirenz (Sustiva, in Atripla), etravirine (Intelence), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir), and saquinavir (Invirase); modafinil (Provigil); nafcillin; nefazodone; phenobarbital; phenytoin (Dilantin, Phenytek); rifabutin (Mycobutin); rifampin (Rifamate, Rifater); rifapentine (Priftin); steroid medications such as dexamethasone (Decadron); telithromycin (Ketek); and voriconazole (Vfend). Many other medications may also interact with axitinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St John's wort.
- tell your doctor if you have a wound that has not healed, or if you have or have ever had bleeding problems; blood clots; high blood pressure; a heart attack; diabetes; high cholesterol levels; bleeding in the stomach or intestines; brain cancer; a pulmonary embolism (blood clot in your lung); a stroke or ministroke (TIA); or heart; liver; or thyroid disease.
- tell your doctor if you are pregnant, plan to become pregnant, or if you plan to father a child. If you are female, you will have to take a pregnancy test before starting treatment and use birth control to prevent pregnancy during your treatment and for 1 week after your final dose. If you are male, you and your female partner should use birth control during your treatment and for 1 week after your final dose. Talk to your doctor about birth control methods that will work for you. If you or your partner becomes pregnant while taking axitinib, call your doctor. Axitinib may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed during your treatment with axitinib and for 2 weeks after your final dose.
- you should know that this medication may decrease fertility in men and women. Talk to your doctor about the risks of taking axitinib.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking axitinib. Your doctor will tell you to stop taking axitinib at least 2 days before your surgery and when it will be safe for you to start taking axitinib again after your surgery.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss a dose of axitinib, skip that dose and take your next dose at the regular time. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Axitinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea

- decrease in appetite or ability to taste things
- weight loss
- nausea
- vomiting
- constipation
- tiredness
- weakness
- change in the sound of your voice
- redness, pain, numbness, tingling, or itching or peeling of the skin on your hands and feet
- cough
- joint or muscle pain
- mouth sores
- stomach pain
- heart burn
- headache
- dizziness
- rash
- itching
- dry skin
- feeling hot or cold
- pale skin
- fast heart beat
- hair loss
- ringing in the ears
- thirst
- hemorrhoids
- wound or cut that will not heal

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical help:

- severe stomach pain
- shortness of breath
- swelling in hands or feet
- unusual bleeding or bruising

- black and tarry stools
- red blood in stools
- bloody vomit
- vomiting material that looks like coffee grounds
- chest pain or pressure
- pain in the arms, back, neck, or jaw
- swelling, tenderness, warmth, or redness of a leg
- sudden numbness or weakness of face, arm, or leg (especially on one side of the body)
- sudden confusion, trouble speaking or understanding
- sudden trouble seeing in one or both eyes
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden severe headache with no known cause
- seizure
- loss of vision

Axitinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- dizziness
- seizures
- coughing up blood

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to axitinib. Your doctor will also check your blood pressure regularly during your treatment with axitinib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Inlyta[®]

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