







## **AXITINIB**

### Name of your medication

Generic name — axitinib (AK-sih-TIH-nib) Brand name — Inlyta® (in-LY-tuh)

#### Common uses

Dose and schedule

Axitinib is used to treat patients with advanced kidney cancer (renal cell carcinoma).

Axitinib may also be used for other treatments.

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Taking axitinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of axitinib is 5 milligrams (5 mg) to be taken by mouth at a scheduled time twice daily (about 12 hours apart).
- Axitinib can be taken with or without food with a full glass of water, but at the same time each day.
- Axitinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow axitinib, talk to your care provider or pharmacist for possible options.
- ☐ If you miss a dose of axitinib, **do not** take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.
- ☐ If you need to have surgery, tell your care provider you are taking axitinib. Axitinib may need to be stopped until your wound heals after some surgeries.

### **Drug and food interactions**

- Axitinib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with axitinib. Avoid eating or drinking these during treatment with axitinib.
- ☐ Talk with your care team or pharmacist before taking new medications or supplements or receiving any vaccines.









### **AXITINIB**

### Storage and handling

Handle axitinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ☐ Store axitinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep axitinib out of reach of children and pets.
- Leave axitinib in the provided packaging until it is ready to be taken.
- Whenever possible, give axitinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give axitinib to you, they also need to follow these steps:
  - 1. Wash hands with soap and water.
  - 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
  - 3. Gently transfer the axitinib from its package to a small medicine or other disposable cup.
  - 4. Administer the medicine immediately by mouth with water.
  - 5. Remove gloves and do not use them for anything else.
  - 6. Throw gloves and medicine cup in household trash.
  - 7. Wash hands with soap and water.
- ☐ If a daily pill box or pill reminder will be used, contact your care team before using:
  - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
  - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn
- If you have any unused axitinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of axitinib.
- If you are traveling, put your axitinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.









## **AXITINIB**

### **Side Effects of Axitinib**

Below are common side effects that have been known to happen in about one third or more of patients taking axitinib are listed on the left side of this table. You <u>MAY NOT</u> experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

| Management  |  |  |  |  |  |
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| <ul> <li>Monitor how many bowel movements you have each day.</li> <li>Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake.</li> <li>Eat small, frequent meals throughout the day rather than a few large meals.</li> <li>Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast).</li> <li>Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains).</li> <li>Avoid foods that cause gas (e.g., broccoli, beans).</li> <li>Avoid lactose-containing foods (e.g., yogurt, milk).</li> <li>Avoid spicy, fried, and greasy foods.</li> </ul> |  |  |  |  |  |
| Contact your provider if any of the following occur:  The number of bowel movements you have in a day increases by four or more.  You feel dizzy or lightheaded.  |  |  |  |  |  |
| Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.  |  |  |  |  |  |
| Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:  Decreased amount of urination  Unusual swelling in your legs and feet   |  |  |  |  |  |
| <ul> <li>Changes in some laboratory values may occur and should be monitored by a simple blood test.</li> <li>You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem.</li> <li>More severe changes may occur, which can be a sign of a serious problem.</li> <li>Notify your care provider if you have any of the following:</li> <li>Shortness of breath</li> <li>Chest discomfort</li> <li>Weakness or fatigue</li> <li>New aches and pains</li> <li>Headaches</li> <li>Dizziness</li> <li>Swelling of your legs or feet</li> </ul>  |  |  |  |  |  |
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| Possible Side Effect  | Management  |  |  |  |  |  |
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| Increased blood<br>pressure   | Routinely take your blood pressure. Record your blood pressure in a journal/diary and report these to your physician. Contact your care provider for high blood pressure or if the following symptoms occur:  Headache Dizziness Chest pain Shortness of breath Fluid retention, weight gain, or swelling   |  |  |  |  |  |
| Fatigue   | You may be more tired than usual or have less energy.  Stay as active as possible, but know it is okay to rest as needed, too.  Try to do some activity every day.  Plan your activities, and do them at a time of day when you feel a bit more energetic.  Avoid operating heavy machinery if you feel too tired.  |  |  |  |  |  |
| Decreased appetite or<br>weight loss  | <ul> <li>Talk to your care provider if you notice a decrease in weight while taking this medication.</li> <li>When you do not feel like eating, try the following:</li> <li>Eat small, frequent meals instead of three large meals each day.</li> <li>Keep snacks nearby so you can eat when you feel hungry.</li> <li>Take liquid nutritional supplements.</li> <li>Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.</li> </ul>     |  |  |  |  |  |
| Decreased<br>hemoglobin, part of<br>the red blood cells that<br>carry iron and oxygen | Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.  Try to get 7–8 hours of sleep per night. Avoid operating heavy machinery if you feel too tired. Find a balance between work and rest. Stay as active as possible, but know that it is okay to rest as needed. You might notice that you are more pale than usual.  Let your care provider know right away if you experience any of the following: Shortness of breath Dizziness Palpitations |  |  |  |  |  |

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| Possible Side Effect   | Management   |  |  |  |
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| Decreased white<br>blood cells (WBCs)<br>and increased risk for<br>infection | Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.  Wash your hands often, especially before eating and after using the bathroom.  Avoid crowds and people with fevers, flu, or other infection.  Bathe regularly to keep good personal hygiene.  Contact your care provider if you experience any signs or symptoms of an infection:  Fever (temperature more than 100.4°F or 38°C)  Chills  Sore throat  Burning with urination  Unusual tiredness  A sore that becomes red, is draining, or does not heal  Check with your care provider before taking any medicine for a fever or chills.  |  |  |  |
| Nausea or vomiting   | <ul> <li>Eat and drink slowly.</li> <li>Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake.</li> <li>Eat small, frequent meals throughout the day rather than a few large meals.</li> <li>Eat bland foods; avoid spicy, fried, and greasy foods.</li> <li>Avoid vigorous exercise immediately after eating.</li> <li>Don't lie down immediately after eating.</li> <li>Avoid strong odors.</li> <li>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help.</li> </ul>   |  |  |  |
| Voice changes or hoarseness  | These changes are not permanent and should go away during the time you are not taking the medication.  |  |  |  |
| Pain or discomfort on<br>hands and/or feet                                   | <ul> <li>Hand-foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and soles of the feet. It can appear as a rash, calluses, peeling skin, increased sensitivity to heat, or a "pins and needles" sensation. Let your care provider know right away if you experience this side effect. To prevent HFS, you can do the following:</li> <li>Keep hands and feet moisturized with a nonfragranced moisturizing cream.</li> <li>Urea 10% or 20% cream may be helpful.</li> <li>Avoid exposure to hot water on the hands and feet in showers or baths that may dry out the skin or by doing dishes.</li> <li>Avoid tight-fitting shoes or socks.</li> <li>Avoid excess rubbing on hands and feet unless putting on lotion</li> <li>Wear gloves when working with your hands.</li> </ul> |  |  |  |

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| <ul> <li>Practice good mouth care using the following practices:</li> <li>Rinse your mouth frequently.</li> <li>Brush your teeth with a soft toothbrush or cotton swab after meals.</li> <li>Use a mild, non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water.</li> <li>If you have sores in your mouth, avoid using tobacco products, alcohol, or mouthwashes that contain alcohol.</li> </ul> | Possible Side Effect | Management   |
|---|----------------------|--|
| Call your care provider if you experience pain or sores in your mouth or throat.  |                      | <ul> <li>Rinse your mouth frequently.</li> <li>Brush your teeth with a soft toothbrush or cotton swab after meals.</li> <li>Use a mild, non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water.</li> <li>If you have sores in your mouth, avoid using tobacco products, alcohol, or mouthwashes that contain alcohol.</li> </ul> |

#### Serious side effects of axitinib

- Axitinib can increase your risk of having a stroke. Be aware of the signs of a stroke and seek medical attention immediately at the first sign of a stroke.
- Axitinib can increase your risk of having a heart attack. Be aware of the signs of a heart attack and seek medical attention immediately at the first sign of a heart attack.
- Axitinib can cause cuts or wounds to heal more slowly. Tell your care team if you have a wound that doesn't heal properly. Also tell your care team if you have planned surgery or dental procedure, as axitinib should be stopped prior to your surgery. Your doctor may restart axitinib after your surgical wound has healed.
- Axitinib may cause problems with your thyroid. Speak to your care team to know when you need to have blood tests to monitor your thyroid. Your provider may prescribe medication to keep your thyroid working properly.
- Axitinib may rarely cause a tear or hole in your intestine, called bowel perforation. Speak to your care team right away if you have a high fever, or nausea, vomiting, or severe stomach pain.
- ☐ There is a low risk that you may develop a rare condition called posterior reversible leukoencephalopathy syndrome (PRES) while taking axitinib. Seek care immediately if you have severe headaches, seizures, confusion, or changes in vision.
- You may be at a higher risk of bleeding while taking axitinib. Contact your care team if you notice frequent nose bleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after five minutes of pressure.
- Axitinib can increase your risk of having a blood clot. Seek immediate medical attention if you have sudden swelling in an arm or leg, have chest pain, or trouble breathing.
- Axitinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- □ Axitinib can increase your risk of having major adverse cardiovascular events (MACE). Speak to your care team about signs and symptoms of MACE including new or worsening chest pain, trouble breathing, or swelling in your hands or legs. Seek immediate medical attention if you experience any signs or symptoms of MACE.









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| Axitinib may be harmful to your kidneys. Speak to your care team to know when you need to have blood tests to monitor |
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| your kidneys. Contact your care team if you notice swelling in your legs and feet or decreased amount of urination.   |

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

### Handling body fluids and waste

Because axitinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take axitinib, it is important to follow the instructions below every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- ☐ Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- □ Toilet and septic systems
  - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
  - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
  - Wash hands with soap and water after using the toilet.
- ☐ If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- ☐ If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or axitinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- ☐ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

#### Pregnancy, sexual activity, and contraception

- □ Women should not become pregnant, and men should not get a partner pregnant, while taking axitinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 week after the last dose of axitinib.
- ☐ Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking axitinib and for 2 weeks after the last dose of axitinib.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.









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| ☐ Talk with your care provider about the proc   | ess for obtaining your axitinib.  |
|---|---|
|   | (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)   |
| Additional resources  |   |
| Product website: www.inlyta.com Product prescribing information: http: Product resources: www.inlyta.com/su | ://labeling.pfizer.com/ShowLabeling.aspx?id=759 pport-resources/additional-support  Updated - November 10, 2023 |
| Additional instructions   |   |
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