

For the Patient: Axitinib **INLYTA®** Other names:

- **Axitinib** (ax i' ti nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth. The tablet contains lactose.
- Blood tests and blood pressure measurements may be taken regularly during treatment. The dose and timing of your axitinib may be changed based on the test results and/or other side effects.
- It is important to take axitinib exactly as directed by your doctor. Make sure you understand the directions. You may be given tablets of more than one strength to make the right dose.
- You may take axitinib with food or on an empty stomach as long as you take it the same way with each dose.
- If you miss a dose of axitinib, skip the missed dose and continue at your next usual dosing time. Do not take any doses to make up for the missed dose.
- If you **vomit** the dose of axitinib within 30 minutes of taking it, skip the missed dose and continue at your next usual dosing time. Do not take any doses to make up for the missed dose. Let your doctor know as a medication to prevent nausea may be required for future doses.
- Other drugs such as ketoconazole (NIZORAL®), rifampin (RIFADIN®), and antacids (MAALOX®) may interact with axitinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs or herbal products.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with axitinib.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of axitinib.
- Axitinib may cause **sterility** in men and women. If you plan to have children, discuss this with your doctor before being treated with axitinib
- Axitinib may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with axitinib. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.

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- **Store** axitinib tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** doctors, dentists, and other health professionals that you are being treated with axitinib before you receive any treatment from them.
- If you are planning to have surgery, you should stop taking axitinib 24 hours prior to surgery. Do not restart axitinib until the surgical wound is fully healed. This helps to lower the risk of bleeding and may prevent problems with wound healing after surgery.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

| SIDE EFFECTS | MANAGEMENT | | |
|---|--|--|--|
| Nausea and vomiting may sometimes occur. | You may be given a prescription for antinausea drug(s) to take before your chemotherapy treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in Food Choices to Help Control Nausea.* | | |
| Skin rash, dryness, or itching may sometimes occur. | • If itching is very irritating, call your doctor. Otherwise, make sure to mention it at your next visit. | | |
| Diarrhea may commonly occur. | If diarrhea is a problem: Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in Food Ideas to Help Manage Diarrhea.* Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID@tablets just before your axitinib dose. | | |
| Constipation may sometimes occur. | Exercise if you can. Drink plenty of fluids. Try ideas in Suggestions for Dealing with Constipation.* | | |

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Revised:

| SIDE EFFECTS | MANAGEMENT | |
|---|--|--|
| High blood pressure may sometimes occur. This can happen very quickly after starting treatment. | Your blood pressure will be checked during your visits to your doctor. | |
| | You may be asked to check your blood pressure frequently between visits. | |
| | Your doctor may give you medication if your blood pressure is high. | |
| | Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose. | |
| Your white blood cells may decrease | To help prevent infection: | |
| during your treatment. White blood cells protect your body by fighting bacteria | Wash your hands often and always after using the bathroom. | |
| (germs) that cause infection. When they are low, you are at greater risk of | Avoid crowds and people who are sick. | |
| having an infection. | Stop taking axitinib and call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine. | |
| Your platelets may decrease during your treatment. Platelets help to make your blood clot when you hurt yourself. You may bruise or bleed more easily than usual. | To help prevent bleeding problems: | |
| | Try not to bruise, cut, or burn yourself. | |
| | Clean your nose by blowing gently. Do not pick your nose. | |
| | Avoid constipation. | |
| | Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene. | |
| | Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. | |
| | Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). | |
| | For minor pain, try acetaminophen (e.g., TYLENOL®), to a maximum of 4 g (4000 mg) per day. | |

| SIDE EFFECTS | MANAGEMENT | | |
|---|---|--|--|
| Sore mouth may sometimes occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection. | Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. | | |
| | Make a mouthwash with ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day. | | |
| | Try the ideas in Food Ideas to Try with a Sore Mouth.* | | |
| Hand-foot skin reaction may sometimes occur during axitinib treatment. The palms of your hands and soles of your feet may tingle, become red, numb, painful, or swollen. Skin may also become dry or itchy. You may not be able to do your normal daily activities if blisters, severe pain, or ulcers occur. | Avoid tight-fitting shoes or rubbing pressure to hands and feet, such as the caused by heavy activity. Avoid tight-fitting jewellery. Clean hands and feet with lukewarm water and gently pat to dry; avoid hot water. Apply a sunscreen with an SPF (sun protection factor) of at least 30. Apply lanolin-containing creams (e.g., BAG BALM®, UDDERLY SMOOTH®) thands and feet, liberally and often. Tell your cancer doctor or your nurse at the next visit if you have any signs of | | |
| Headache may sometimes occur. | hand-foot skin reaction as your dose may need to be changed. Take acetaminophen (e.g., TYLENOL®) | | |
| | every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. | | |
| Muscle, joint or limb pain may sometimes occur. | You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your doctor if the pain interferes with your activity. | | |
| Sugar control may sometimes be affected in diabetics. | Check your blood sugar regularly if you are diabetic. | | |
| Taste alteration may sometimes occur. | Try the ideas in Food Ideas to Cope with Taste and Smell Changes.* | | |
| Loss of appetite and weight loss can sometimes occur. | Try the ideas in Food Ideas to Help with Decreased Appetite.* | | |

| SIDE EFFECTS | MANAGEMENT | | |
|--|---|--|--|
| Tiredness and lack of energy may sometimes occur. | Do not drive a car or operate machinery if you are feeling tired. | | |
| | Try the ideas in Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.* | | |
| Hair loss is rare with axitinib. If you lose hair, it will grow back once you stop treatment with axitinib. Colour and texture may change. | If hair loss is a problem, refer to For the Patient: Hair Loss Due to Chemotherapy.* | | |
| Blood clots may rarely occur. Signs to watch for include tenderness or hardness over a vein, calf tenderness, sudden onset of cough, chest pain, or shortness of breath. | To help prevent blood clots: Keep active. Drink plenty of fluids. Avoid tight clothing. Do not sit with your legs crossed at the knees. | | |

^{*}Please ask your chemotherapy nurse or pharmacist for a copy.

STOP TAKING AXITINIB AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of a stroke such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of an infection such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising; coughing up blood, or nosebleeds.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness, sudden onset of cough, chest pain, or shortness of breath.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- Seizures or loss of consciousness.
- Severe headache that does not go away, or occurs with vomiting, confusion, or changes in eyesight.
- Sudden abdominal pain or tenderness.

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SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower
- Signs of **thyroid problems** such as unusual weight gain or loss, feeling hot or cold, deepened voice, or unusual tiredness or weakness.
- Numbness or tingling in feet or hands, or trouble walking.
- Changes in eyesight.
- Increased **sore throat** or **mouth** that makes it difficult to swallow comfortably.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR **BOTHER YOU:**

- Uncontrolled nausea, vomiting, or diarrhea.
- Loss of appetite, upset stomach, or weight changes.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Easy bruising or minor bleeding.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Skin rash or itching.
- Hemorrhoids.
- Cough, hoarseness, or trouble speaking.
- Dizziness, ringing in your ears, or hearing problems.
- Wounds or sores that do not heal or are slow to heal.
- For diabetics: uncontrolled blood sugars.

| REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR | | |
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