

Axitinib (Inlyta)

About This Medicine

Axitinib is used to treat cancer. It is given by mouth (orally).

Possible Side Effects

- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Tiredness and weakness
- · Weight loss
- Decreased appetite (decreased hunger)
- Voice changes/hoarseness
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- · High blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with axitinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe high blood pressure
- Congestive heart failure, which can be life threatening your heart is not pumping blood as well as it should be, and fluid can build up in your body. Other severe and life-threatening heart conditions can happen when axitinib is given in combination with other therapies to treat cancer.
- Increased protein in your urine, which can affect how your kidneys work.
- Blood clots and events such as stroke and heart attack, which can be life-threatening. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Abnormal bleeding which can be life-threatening symptoms may be coughing up blood, throwing
 up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy
 menstrual flow, nosebleeds or any other unusual bleeding.



- Perforation or fistula an abnormal hole in your stomach, intestine, esophagus, or other organ, which can be life-threatening.
- Changes in your thyroid function
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a
 headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. If you start
 to have any of these symptoms let your doctor know right away.
- · Changes in your liver function
- Slow wound healing

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

 Axitinib may cause slow wound healing. It should not be given within at least 2 days of planned surgery and for at least 2 weeks and until adequate wound healing after major surgery. If you must have emergency surgery or have an accident that results in a wound, tell the doctor that you are on axitinib.

How to Take Your Medicine

- Swallow the medicine whole with a full glass of water, approximately 12 hours apart.
- You can take the medicine with or without food.
- **Missed dose**: If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- Handling: Wash your hands with soap and water, before and after handling your medicine. Your
 caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- Storage: Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.



- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms
- To help with decreased appetite, eat small, frequent meals and include a source of protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of axitinib in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter
 medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before
 starting this medicine as there are known medicine interactions with axitinib. Also, check with your
 doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary
 supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking axitinib as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness and/or weakness that interferes with your daily activities
- A headache that does not go away
- · Blurry vision or other changes in eyesight
- Confusion
- · Extreme tiredness and/or coma



- Trouble understanding
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. If you or your family member suspects you are having a seizure, call 911 right away.
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. If you have any of these symptoms for 2 minutes, call 911.
- Wheezing and/or trouble breathing
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. If any of these symptoms last 2 minutes, call 911.
- Severe pain in your abdomen that does not go away
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicine
- Throwing up more than 3 times a day
- Difficulty swallowing
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Your leg is swollen, red, warm and/or painful
- Swelling of the legs, feet, or ankles
- Foamy or bubbly-looking urine
- Signs of increased thyroid function: unexplained weight loss, sweating, irritability, feeling that your heart is beating fast or in a not normal way (palpitations)
- Signs of low thyroid function: tiredness, unexplained weight gain, hair loss, dry skin, constipation, increased sensitivity to cold
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Weight gain of 5 pounds in one week (fluid retention) or unexplained weight gain
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

 Pregnancy warning: This medicine can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment



and for 1 week after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 week after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner. When receiving axitinib in combination with other agents, please refer to the medicine guide of those agents for more specific information.

- **Breastfeeding warning**: Women should not breastfeed during treatment and for 2 weeks after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby. When receiving axitinib in combination with other agents, please refer to the medicine guide of those agents for more specific information.
- Fertility warning: In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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