



# Tips To Help Manage Certain Side Effects With INLYTA<sup>®</sup> (axitinib)

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The tips in this guide are based on published general guidelines for managing certain side effects that are common among patients with advanced renal cell carcinoma (RCC) or other cancers. [Side effect tips](#) begin on page 8. You can find a list of possible serious side effects in the [Important Safety Information](#) on pages 3 to 6.

Studies show that treatment can have both benefits and risks. Keep in mind that while taking INLYTA, whether alone or in combination with pembrolizumab, side effects are expected. Not all side effects are manageable. Dose interruptions and/or reductions may be needed during treatment with INLYTA, pembrolizumab, or both. Be sure to pay attention to all your side effects. They can be important signs that let you and your healthcare provider know what is happening in your body.

Before starting INLYTA, tell your healthcare provider how you are feeling and about any side effects you have had from other medications and treatments. As you start taking INLYTA, let your healthcare provider know if you notice any side effects or a change in how you feel. Also tell your healthcare provider if you notice any side effects that are not listed in this guide.

If your healthcare provider prescribes INLYTA for you to be taken in combination with pembrolizumab, also read the Medication Guide for pembrolizumab.

## INDICATIONS

INLYTA is a prescription medicine used to treat kidney cancer that has spread or cannot be removed by surgery (advanced renal cell carcinoma or RCC):

- in combination with pembrolizumab as your first treatment
- alone when 1 prior drug treatment regimen for your RCC has not worked

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

Please see [Important Safety Information](#) on pages [3 to 6](#). Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](#).

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axitinib  
1mg and 5mg tablets

## Discussing side effects with your healthcare provider

Treating advanced kidney cancer can bring a new set of challenges, including side effects from your treatment. A side effect happens when your treatment affects healthy cells, tissues, or organs.

Side effects can vary from person to person and from treatment to treatment. Some side effects may happen right when you start treatment, while others may happen later on. Ask your healthcare provider to explain the side effects of treatment, so you can have a better idea of what to expect. Learn about [side effect tips](#) on page 8.

## Understanding the most common side effects

In a clinical trial of 432 patients taking INLYTA® (axitinib) with pembrolizumab versus 429 patients taking a medicine called sunitinib, side effects were studied. The side effects listed below were the most common experienced among patients. For more information on this clinical trial, visit [INLYTA.com](http://INLYTA.com).

Side effects	INLYTA (axitinib) + pembrolizumab	sunitinib
Diarrhea	56%	45%
Feeling tired or weak	52%	51%
High blood pressure	48%	48%
Liver problems	39%	25%
Low levels of thyroid hormone	35%	32%
Decreased appetite	30%	29%
Redness, itching or peeling of your skin on your hands and feet	28%	40%
Nausea	28%	32%
Mouth sores or swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina	27%	41%
Hoarseness	25%	3.3%
Rash	25%	21%
Constipation	21%	15%
Cough	21%	14%

For information on side effects that occurred in patients taking INLYTA alone, please see [page 6](#), or the full [Prescribing Information](#).

Please see *Important Safety Information*, including information on serious side effects, on pages [3 to 6](#). Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](http://INLYTA.com).



## IMPORTANT SAFETY INFORMATION

**Before taking INLYTA® (axitinib), tell your healthcare provider about all of your medical conditions, including 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 problems, including heart failure
- have an unhealed wound
- plan to have surgery or have had a recent surgery. You should stop taking INLYTA for at least 2 days before planned surgery

**For females, tell your healthcare provider if you:**

- are pregnant or plan to become pregnant. Taking INLYTA during pregnancy can harm your unborn baby. You should not become pregnant during treatment with INLYTA.
- are able to become pregnant. You should have a pregnancy test before you start treatment with INLYTA. Use effective birth control during treatment and for 1 week after your last dose of INLYTA. Talk to your healthcare provider about birth control methods that you can use to prevent pregnancy during this time.
- are breastfeeding or plan to breastfeed. It is not known if INLYTA passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of INLYTA.

**For males with female partners who are able to become pregnant:**

- use effective birth control during treatment and for 1 week after your last dose of INLYTA.
- if your female partner becomes pregnant during your treatment with INLYTA, tell your healthcare provider right away.

INLYTA may cause **fertility problems** in males and females, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider 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.

Talk with your healthcare provider before you start taking any new medicine. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

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

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Please see Important Safety Information on pages [3 to 6](#). Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](#).



## IMPORTANT SAFETY INFORMATION (cont'd)

INLYTA® (axitinib) may cause serious side effects, including:

- **High blood pressure (hypertension).** High blood pressure is common with INLYTA and may sometimes be severe. Your healthcare provider should check your blood pressure regularly during treatment with INLYTA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose, or stop your treatment with INLYTA
- **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 healthcare provider 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 healthcare provider 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 healthcare provider should check you 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 healthcare provider 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-area (abdominal) pain or stomach-area pain that does not go away
  - vomit blood
  - red or black stools

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Please see Important Safety Information on pages [3 to 6](#). Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](http://INLYTA.com).



## IMPORTANT SAFETY INFORMATION (cont'd)

- **Thyroid gland problems.** Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment with INLYTA® (axitinib). Tell your healthcare provider 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
  
- **Risk of wound healing problems.** Wounds may not heal properly during INLYTA treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with INLYTA.
  - You should stop taking INLYTA at least 2 days before planned surgery
  - Your healthcare provider should tell you when you may start taking INLYTA again after surgery
  
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen during treatment with INLYTA. Call your healthcare provider right away if you get:
  - headache
  - seizures
  - weakness
  - confusion
  - high blood pressure
  - blindness or change in vision
  - problems thinking
  
- **Protein in your urine.** Your healthcare provider should check your urine for protein before and during your treatment with INLYTA. If you develop protein in your urine, your healthcare provider may decrease your dose of INLYTA or stop your treatment.
  
- **Liver problems.** Your healthcare provider will do blood tests before and during your treatment with INLYTA. Your healthcare provider may delay or stop your treatment with INLYTA if you develop severe liver problems.
 

Tell your healthcare provider right away if you have any of the following symptoms:

  - yellowing of your skin or the whites of your eyes
  - severe nausea or vomiting
  - pain on the right side of your stomach area (abdomen)
  - dark urine (tea colored)
  - bleeding or bruising more easily than normal

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Please see Important Safety Information on pages [3 to 6](#). Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](http://INLYTA.com).



## IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of INLYTA® (axitinib) with pembrolizumab include:

- diarrhea
- feeling tired or weak
- high blood pressure
- liver problems
- low levels of thyroid hormone
- decreased appetite
- rash, redness, itching or peeling of your skin on your hands and feet
- nausea
- mouth sores or swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- hoarseness
- rash
- cough
- constipation

**Important information:** If your healthcare provider prescribes INLYTA for you to be taken with pembrolizumab, also read the [Medication Guide for pembrolizumab](#).

The most common side effects of INLYTA when used alone include:

- diarrhea
- high blood pressure
- feeling tired or weak
- decreased appetite
- nausea
- hoarseness
- rash, redness, itching or peeling of your skin on your hands and feet
- decreased weight
- vomiting
- constipation

These are not all of the possible side effects of INLYTA. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088).

## Managing side effects with your healthcare provider

While you're taking INLYTA® (axitinib) with pembrolizumab, side effects are expected. Talk to your healthcare team about your side effects so they can help you manage them.

**Based on the severity of your side effects, your healthcare provider may recommend:**



Lifestyle adjustments and medicines to help manage certain side effects



Lowering your dose to help resolve or reduce the severity of your side effects



Taking a break from treatment for a period of time to help resolve or reduce the severity of your side effects so that you can resume treatment



Changing treatments if your side effects become difficult to manage

### A HELPFUL TIP

Deciding when to call your healthcare team about your side effects can often be a challenging decision. If you ever find yourself in this situation, remember that all information regarding your treatment experience is helpful to your healthcare team. Even before you experience side effects, it can be beneficial to get the conversation started. Some initial questions may be:

- If I have a side effect, should I report them by calling the office, through a patient portal, or via another form of communication that I should be aware of?
- What side effects should I expect on treatment?
- What is high blood pressure? How often should I check my blood pressure?

If side effects become too severe over time, they could cause permanent discontinuation from treatment. **Make sure that you talk with your healthcare team about your side effects** so they can help you manage them early on.

## Tips to help manage certain side effects

### High blood pressure

INLYTA® (axitinib), when taken alone or in combination with pembrolizumab, may cause your blood pressure to rise. In a clinical trial of INLYTA alone, hypertension occurred as early as 4 days into treatment. On average, this increase was seen within the first month of treatment.

Follow your healthcare provider's instructions about having your blood pressure checked regularly. Call your healthcare provider if your blood pressure is too high.

Your healthcare provider may recommend that you:

- Get regular exercise
- Lower your alcohol intake
- Keep your weight under control and lower the amount of sodium you eat in your food

**If you develop blood pressure problems, your healthcare provider may lower your dose, stop your treatment, or prescribe medicine to treat your high blood pressure. Tell your healthcare provider if you have high blood pressure or a history of heart disease.**



Keep your weight under control and limit your alcohol and sodium consumption



Monitor severe headaches, shortness of breath, or nosebleeds



Exercise regularly

### Diarrhea

Diarrhea is defined as 3 or more loose or watery stools/bowel movements in 1 day. If you have these symptoms, call your healthcare provider. It is important for you and your healthcare provider to try to manage diarrhea as soon as it begins.

**Diarrhea can be a symptom of a more severe medical condition, so it's important to call your healthcare provider right away. They may give you ways to help manage it and may adjust or stop your treatment if needed.**



Try yogurt containing probiotics



Avoid spicy foods, fatty foods, caffeine, and raw fruits and vegetables



Eat small, frequent meals and foods containing soluble fiber



Drink fluids, such as water, diluted cranberry juice, or broth



Ask your healthcare provider if you can be treated with over-the-counter medications or prescriptions

Let your healthcare provider know right away if you're experiencing any side effect. They may give you tips to help manage it and may adjust or stop your treatment if needed.

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## Feeling tired or weak

While on treatment, you may feel tired or weak. Call your healthcare provider if you have these symptoms. Ask your healthcare provider if there are over-the-counter or prescription medicines that may help you manage your condition.



Take short naps and breaks instead of long ones



Stay as active as possible



Eat well and drink plenty of fluids



Try to maintain normal work and social schedules

## Decreased appetite

During treatment, you may have less desire to eat. But maintaining good nutrition and a healthy weight are important to your overall health. Protein and calories are especially vital to someone with cancer.



Eat several small meals a day, including nutritious snacks that are high in calories and protein



Drink fluids between meals rather than filling up with beverages during meals



Flavor foods with herbs, sugar, or sauces to maximize taste



If taste changes cause you to eat less, try cold or frozen foods to minimize taste

## Nausea

Nausea is defined as feeling as if you are about to throw up. It is best to call your healthcare provider at the first sign of nausea. This is especially important if this symptom keeps you from taking your oral medications or keeping them down. Your healthcare provider may prescribe a medicine for these symptoms.



Eat smaller, more frequent meals



Avoid fatty, fried, spicy, or highly sweet foods



Eat bland foods at room temperature and drink clear liquids

If you vomit, start with small amounts of water, broth, or other clear liquids when you are ready to eat again. If that stays down, then try soft foods. Some examples include gelatin, pudding, yogurt, strained soup, or strained cooked cereal. Slowly work up to eating solid food. Make sure that you do not eat any food that you are allergic to.

Let your healthcare provider know right away if you're experiencing any side effect. They may give you tips to help manage it and may adjust or stop your treatment if needed.

## Hoarseness

Hoarseness is when you have a weak, rough, or harsh voice.



Write things down to give your voice a break



Drink plenty of water and avoid irritants like dust, smoke, alcohol, or industrial chemicals



Remember to avoid shouting or whispering

## Skin conditions

Skin conditions, such as rash, redness, itching, or peeling of the skin are other side effects that may occur. You may notice dryness, thickening, calluses, blisters, or cracking of the skin on the palms of your hands and soles of your feet. This is called hand-foot syndrome.



Wear loose, cotton clothes



Clean hands and feet with lukewarm water and gently pat dry



Avoid tight-fitting shoes and jewelry that rub or chafe the hands and feet

## Constipation

Some patients taking INLYTA® (axitinib) experience constipation during treatment. This has the potential to become a serious side effect. Left untreated, constipation can cause a blockage in your intestines, leading to dehydration and even internal damage.



Drink more fluids



Increase physical activity



Talk to your doctor about changing your dose of INLYTA



Take a stool softener



Add fiber to your diet

Let your healthcare provider know right away if you're experiencing any side effect. They may give you tips to help manage it and may adjust or stop your treatment if needed.

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