



Keeping track of side effects when taking INLYTA[®] (axitinib) with pembrolizumab

It's important to pay attention to any side effect you experience while taking INLYTA in combination with pembrolizumab and to let your healthcare provider know about any you experience.

This guide is designed to help you keep track of your side effects throughout treatment and share them with your healthcare provider.

Before starting INLYTA, tell your healthcare provider how you are feeling and about any side effects you have had from other medications and treatments. It's possible that you could experience side effects that are not mentioned in the [Important Safety Information](#). So, as you start taking INLYTA, let your healthcare provider know if you notice any side effects or change in how you feel.

INDICATION

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.

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

Please see [Important Safety Information](#) on pages [4 to 8](#) and full [Prescribing Information](#) and [Patient Information](#) following this guide or at [INLYTA.com](#).



 **Inlyta**[®]
axitinib
1mg and 5mg tablets

Side Effect Tracker



You can find a list of [serious side effects](#) and the most [common side effects](#) of INLYTA (axitinib) when taken in combination with pembrolizumab in the [Important Safety Information](#).

Not all side effects are manageable. Dose interruptions and/or reductions may be needed during treatment with INLYTA, pembrolizumab, or both.

Use the table below to record any side effects or changes in your body that you experience. Then bring this table with you to each appointment so you can discuss your side effects with your healthcare team.

	Date:	How severe? (Choose one) (1 is least severe and 5 is most severe)		Description of side effect:
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		
	___/___/___	1 2 3 4 5		

Side Effect Tracker (continued)

 Date:	How severe? (Choose one) (1 is least severe and 5 is most severe)	 Description of side effect:
___/___/___	1 2 3 4 5	
___/___/___	1 2 3 4 5	
___/___/___	1 2 3 4 5	
___/___/___	1 2 3 4 5	
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___/___/___	1 2 3 4 5	
___/___/___	1 2 3 4 5	
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___/___/___	1 2 3 4 5	

Please see Important Safety Information on pages 4 to 8 and full Prescribing Information and Patient Information following this guide or at INLYTA.com.



IMPORTANT INFORMATION

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

IMPORTANT SAFETY INFORMATION

Before taking INLYTA, 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.

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Please see additional Important Safety Information on pages [5 to 8](#) and full [Prescribing Information](#) and [Patient Information](#) following this guide or at INLYTA.com.



IMPORTANT SAFETY INFORMATION (cont'd)

INLYTA (axitinib) 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.

INLYTA 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
 - shortness of breath
 - trouble talking
 - pain in your arms, back, neck or jaw
 - numbness or weakness on one side of your body
 - headache
 - vision changes

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Please see additional Important Safety Information on pages [6 to 8](#) and full [Prescribing Information](#) and [Patient Information](#) following this guide or at INLYTA.com.



IMPORTANT SAFETY INFORMATION (cont'd)

- **Bleeding.** INLYTA (axitinib) 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
- **Thyroid gland problems.** Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment with INLYTA. 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

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Please see additional Important Safety Information on page [7 to 8](#) and full [Prescribing Information](#) and [Patient Information](#) following this guide or at INLYTA.com.



IMPORTANT SAFETY INFORMATION (cont'd)

- **Risk of wound healing problems.** Wounds may not heal properly during INLYTA (axitinib) 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 way 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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IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of INLYTA 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

These are not all 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 or call [1-800-FDA-1088](tel:1-800-FDA-1088).

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