



How to take INLYTA[®] (axitinib) with pembrolizumab

When taking INLYTA in combination with pembrolizumab, there are a lot of details to understand. This guide provides information on taking INLYTA, including some tips and reminders to keep in mind.

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.

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

Please see Important Safety Information throughout. Click for the full [Prescribing Information](#) and [Patient Information](#) or visit [INLYTA.com](https://www.inlyta.com).

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

INLYTA (axitinib)

Remember to take INLYTA exactly as prescribed by your healthcare provider. They may change your dose if needed, and should check your blood pressure regularly during treatment.

INLYTA is an oral medication that is taken twice daily. It comes in 1-mg and 5-mg tablets. Your healthcare provider will tell you which tablets you should take.



INLYTA can be taken with or without food.



Take INLYTA 2 times a day about 12 hours apart.



Swallow INLYTA tablets whole with a glass of water.



If you vomit or miss a dose of INLYTA, take your next dose at your regular time. Do not take 2 doses at the same time.



If you take too much INLYTA, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking INLYTA?



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



Patients taking INLYTA should avoid St. John's wort. It may reduce the amount of INLYTA in your blood.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

INLYTA (axitinib)

Reminders for taking INLYTA

Here are some things to consider:



Make medicine a part of your daily routine.



Use a weekly or monthly pill organizer.



Plan ahead.



Place your pill bottle in plain sight.



Always carry an extra dose with you.



Use the [treatment tracker](#), a calendar, or a journal to help you keep up with appointments and your medicines.



Ask for a reminder from your caregiver or care team.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Pembrolizumab

Pembrolizumab is an infusion therapy that is administered by a healthcare provider through an intravenous (IV) line. Treatments usually take place at your healthcare provider's office or an infusion clinic, and are given over 30 minutes every 3 or 6 weeks.

Tips for pembrolizumab treatment days

Before getting an infusion, it can help to prepare for the day. Bringing a friend or loved one with you for support can help. You can also pack a bag ahead of time to bring with you. Here are some things to consider:



In case you get dehydrated, bring water, lip balm, and hand lotion for dry hands.



Some clinics provide snacks, but you can also bring your own.



To help pass the time, bring books, magazines, or an electronic device such as a tablet or mobile phone.



The clinic may be cold, so bring multiple layers of clothing or a soft blanket.



If it's noisy, bring earplugs or headphones.

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 (cont'd)

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.

IMPORTANT SAFETY INFORMATION (cont'd)

Do not drink grapefruit juice or eat grapefruit. Grapefruit may increase the amount of INLYTA (axitinib) 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
- **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
 - red or black stools (looks like tar)
 - menstrual bleeding or vaginal bleeding that is heavier than normal
 - bruises that happen without a known cause or get larger
 - bleeding that is severe or you cannot control
 - cough up blood or blood clots
 - vomit blood or your vomit looks like “coffee grounds”
 - pink or brown urine
 - unexpected pain, swelling, or joint pain
 - headaches, feeling dizzy or weak

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IMPORTANT SAFETY INFORMATION (cont'd)

- **Heart failure.** Your healthcare provider should check you for signs or symptoms of heart failure regularly during treatment with INLYTA (axitinib). 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
 - shortness of breath
 - swelling of your stomach-area (abdomen), legs or ankles
 - 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
 - weight gain or weight loss
 - feeling hot or cold
 - hair loss
 - your voice deepens
 - 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

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IMPORTANT SAFETY INFORMATION (cont'd)

- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen during treatment with INLYTA (axitinib). 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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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 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 or call [1-800-FDA-1088](tel:1-800-FDA-1088).

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