



Your INLYTA[®] Guide

INLYTA[®] is a prescription medicine used to treat a certain type of kidney cancer called renal cell carcinoma (RCC). It is used when a prior drug treatment has not worked or has stopped working, or if there are unwanted side effects with a prior drug treatment.

Prescribed INLYTA[®] (axitinib) tablets?

Your doctor has prescribed INLYTA[®]. This guide has been provided to help you understand more about INLYTA[®]:

- ▶ How it works
- ▶ How you should take it
- ▶ Possible side effects you should be aware of
- ▶ When to contact your doctor or seek emergency help
- ▶ Advice for self-care
- ▶ How to access the INLYTA[®] assistance programme

This guide does not take the place of talking to your doctor or pharmacist. If you have any questions about your treatment please discuss them with your doctor.

This is a general guide. Please read the Consumer Medicine Information Leaflet available from www.medsafe.govt.nz for further information about INLYTA[®]. If you have any questions about your treatment please discuss them with your doctor.

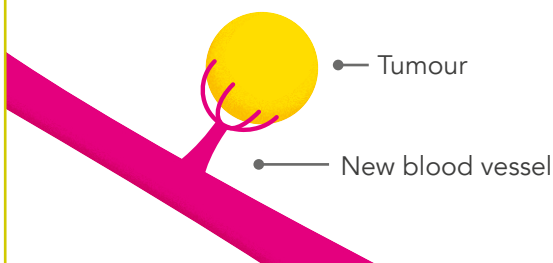
Why you have been prescribed INLYTA®

INLYTA® is used to treat a certain type of kidney cancer called renal cell carcinoma (RCC). It is used when a prior treatment has stopped working.

If you have any questions about why INLYTA® has been prescribed for you, please ask your doctor.

How does INLYTA® work?

INLYTA® is a tyrosine kinase inhibitor. It contains the active substance axitinib. INLYTA® works by reducing the blood supply to the tumour and by slowing down its growth.



How to take INLYTA®

You should take INLYTA® exactly as your doctor instructs you.

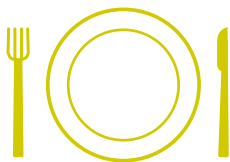
If you do not understand any of the instructions, ask your doctor or pharmacist for help.

INLYTA® tablets should be swallowed whole with a glass of water. INLYTA® can be taken with or without food.

Do not drink grapefruit juice or eat grapefruit while taking INLYTA® as these foods may change the amount of INLYTA® in your body.



Swallow whole
with a glass of water

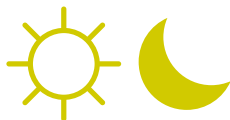


May be taken
with or without food
Do not eat or drink grapefruit

When to take INLYTA®

Take INLYTA® twice a day, about the same time each day to have the best effect.

It will also help you remember when to take it.



Take twice
a day

How much to take

INLYTA[®] is available in 1mg and 5mg tablets. Your doctor will tell you which tablets you should take.

For kidney cancer, the usual starting dose of INLYTA[®] is one 5mg tablet taken two times a day (a total of two tablets each day).

5mg



Your doctor may increase or decrease your dose depending on your response to INLYTA[®].

1mg



How long to take INLYTA[®]

Continue taking INLYTA[®] for as long as your doctor tells you. This medicine helps to control your condition. It is important to keep taking your medicine even if you feel well.

If you miss a dose of INLYTA[®]

If you miss a dose of INLYTA[®], take your next dose at your regular time. Do not take a double dose to make up for the dose that you missed.

If you are unsure what to do, ask your doctor or pharmacist for advice.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much INLYTA[®], immediately telephone your doctor, or the Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Before you take INLYTA®

You must advise your doctor if you currently have, or had in the past, any of the following conditions:

- ▶ High blood pressure
- ▶ Thyroid gland problems
- ▶ Blood clots in your veins and/or arteries (blood vessels) or lungs
- ▶ Stroke or heart attack
- ▶ Bleeding problems
- ▶ An unhealed wound or scheduled surgery
- ▶ Liver problems
- ▶ Serious kidney problems (other than cancer for which you are being treated)
- ▶ Lactose intolerance

Before taking INLYTA® your blood pressure should be well-controlled.

INLYTA[®] and pregnancy

Before starting INLYTA[®] tell your doctor if you are pregnant, are breast-feeding or plan to become pregnant.

INLYTA[®] has the potential to cause infertility.

INLYTA[®] should not be taken during pregnancy. Your doctor will discuss the risks with you.

Both men and women should use effective contraception to prevent pregnancy during treatment with INLYTA[®]. Talk to your doctor about effective contraception options.

If you become pregnant while taking INLYTA[®], tell your doctor immediately.

Do not breastfeed while taking INLYTA[®].

Taking other medicines

Before starting treatment with INLYTA[®], tell your doctor and pharmacist about any other medicines you may be taking, including:

- ▶ All prescription medicines
- ▶ All over-the-counter medicines such as vitamins, herbal supplements or natural therapies you may have purchased without a prescription

Some medicines may be affected by INLYTA[®] or may affect how well INLYTA[®] works. You may need different amounts of your other medicines, or you may have to change to different medicines. Your doctor will provide advice.

It is especially important that you tell your doctor or pharmacist if you are taking any of the following:

- ▶ Dexamethasone, a steroid medicine used to treat dermatitis, asthma and some other conditions
- ▶ Ketoconazole or itraconazole, medicines used to treat fungal infections
- ▶ Clarithromycin or telithromycin, antibiotics used to treat bacterial infections
- ▶ Atazanavir, indinavir, nelfinavir, ritonavir or saquinavir, medicines used to treat HIV infection/AIDS
- ▶ Rifampin or rifabutin, medicines used to treat tuberculosis (TB)
- ▶ Nefazodone, used to treat depression
- ▶ Phenytoin, carbamazepine or phenobarbital, anti-epileptic medicines used to stop seizures or fits
- ▶ Theophylline, used to treat asthma or other lung diseases
- ▶ St John's wort (*Hypericum perforatum*), a herbal medicine used to treat depression and other conditions

Your doctor and pharmacist will have more information on which medicines to be careful with or to avoid while taking INLYTA[®].

Also, it is important to remind your doctor that you are taking INLYTA[®] if you are prescribed any new medicine.

Other things to be aware of

- ▶ You will need regular appointments with your doctor to make sure your treatment with INLYTA[®] is working. Make sure you keep all your appointments.
- ▶ While you are taking INLYTA[®] your blood pressure should be regularly monitored. If you experience high blood pressure, your doctor may prescribe medicine to treat your high blood pressure or they may change your dose of INLYTA[®].
- ▶ You will also have to have regular blood tests to make sure the medicine is working and to check for any side effects (some side effects can only be found when your doctor conducts tests).
- ▶ Until you know how INLYTA[®] affects you, be careful driving, operating machinery or doing jobs that require you to be alert. INLYTA[®] may make some people feel very tired or dizzy.

- ▶ If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.
- ▶ You should stop taking INLYTA® at least 24 hours before any planned surgery. Be sure to tell your surgeon or anaesthetist that you are taking INLYTA®.
- ▶ Tell any other doctors, dentists and pharmacists who treat you that you are taking INLYTA®.

Possible side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking INLYTA®.

Dose interruptions and/or reductions in dose may be needed during treatment with INLYTA®. However, if you experience some of the more serious side effects you may require medical attention. Be sure to talk to your doctor about any side effects you experience.

It can be difficult to tell whether side effects are the result of taking INLYTA®, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Side effects associated with INLYTA®

More common:

- ▶ diarrhoea
- ▶ high blood pressure
- ▶ tiredness
- ▶ loss of appetite
- ▶ nausea (feeling sick) or vomiting
- ▶ hoarseness, change in your voice
- ▶ tingling or rash on palms of hands or soles of feet
- ▶ weight loss
- ▶ constipation
- ▶ low thyroid hormone levels (symptoms include being more sensitive to cold, unintentional weight gain and lack of energy)
- ▶ soreness or burning of the mouth, tongue or throat
- ▶ shortness of breath, cough
- ▶ stomach ache, indigestion
- ▶ headache
- ▶ pain in hands or feet
- ▶ muscle pain, joint pain
- ▶ change in sense of taste
- ▶ rash, dry, red, scaly or itchy skin
- ▶ dizziness
- ▶ dehydration
- ▶ nose bleeding
- ▶ piles or bleeding from the back passage
- ▶ hair loss
- ▶ unusual urine colour
- ▶ ringing or sound in the ears
- ▶ weakness

Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects not listed above may also occur in some people.

Possible side effects

(cont.)

Coping with side effects

Most side effects associated with INLYTA® can be managed. There are many treatment options that can minimise or prevent the side effects of INLYTA®.

Tell your doctor or pharmacist if you have any side effect that bothers you or that does not go away. They can provide advice.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- ▶ high blood pressure (symptoms may include headaches, dizziness, blurred vision, nausea and vomiting)
- ▶ foamy and frothy urine with swelling abdomen, legs or eyes
- ▶ swelling of feet or legs, leg pain, cough

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- ▶ chest pain or pressure, pain in your arms, back, neck or jaw; shortness of breath
- ▶ numbness or weakness on one side of your body, loss of coordination
- ▶ trouble speaking, seeing or swallowing
- ▶ headache, confusion, trouble seeing, seizures or fits
- ▶ severe stomach pain with vomiting and fever

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

If you wish to report an adverse event, please contact Pfizer Drug Safety Phone: 0800 734 260 or Email: AUS.AEReporting@pfizer.com

Advice for self-care

- ▶ Drink plenty of water, unless you are instructed otherwise.
- ▶ Eat foods that may help reduce diarrhoea.
- ▶ Monitor your blood pressure.
- ▶ Wash your hands often to avoid infection.
- ▶ Use an electric razor and a soft toothbrush to minimise bleeding.
- ▶ Avoid contact sports or activities that could cause injury.
- ▶ To reduce nausea eat small, frequent meals.
- ▶ Avoid sun exposure and wear SPF 15 (or higher) sunblock and protective clothing.
- ▶ Avoid alcohol.
- ▶ Get plenty of rest.
- ▶ Maintain good nutrition.

Ask your doctor or pharmacist to answer any questions you may have.

How can I work with my healthcare team?

Learn about your disease and treatment so you can help your healthcare team help you.

Understanding your treatment and how it affects you will help you to provide relevant information to your healthcare team. This helps your doctor give you the best advice and treatment. Ask each member of your healthcare team – oncologist, oncology nurse, pharmacist, therapist and others – about their role in your treatment program so you can direct your questions to the appropriate person.

INLYTA[®] (axitinib) Assistance Program

To help make INLYTA[®] more affordable for you, Pfizer has developed the INLYTA[®] Assistance Program. This program will be available through your healthcare provider and may help reduce the overall cost of your treatment.

Pay for seven months of INLYTA[®] and, thereafter, INLYTA[®] at No Charge* (criteria apply)

The INLYTA[®] Assistance Program provides your INLYTA[®] at No Charge, after seven months of INLYTA[®] therapy has been purchased from a New Zealand pharmacy. It is important to note that the following eligibility criteria must be met to be eligible for this program.*Speak to your doctor to see if you are eligible.

To be eligible for the INLYTA[®] Assistance Program you must:

- ▶ Have advanced renal cell carcinoma and failed on one prior systemic therapy.
- ▶ Have purchased seven months of INLYTA[®] therapy from a New Zealand retail pharmacy and be able to provide proof of purchase with the INLYTA[®] Assistance Program application form.
- ▶ Your doctor must have completed an application form and sent through clinical proof of your condition, that you have failed on one prior systemic therapy and that you are progression free after seven months of INLYTA[®] therapy.

*Pfizer will provide INLYTA[®] at No Charge (a dispensary fee may apply), to patients with advanced renal cell carcinoma who have failed on one prior systemic therapy **AND** who have completed and provided proof of purchase of seven months of INLYTA[®] therapy **AND** remain progression free. The treating Physician will need to complete the renewal form yearly from the date signed by the treating physician and send through to Pfizer as outlined in the renewal criteria. INLYTA[®] will be supplied at the same dosage as purchased during the first seven months of therapy. Any increase in dose will be at the expense of the patient.

INLYTA Tablets

INLYTA (axitinib) is an unfunded prescription medicine used to treat renal cell carcinoma, a type of kidney cancer. INLYTA has risks and benefits. Use strictly as directed. Consult your doctor to see if INLYTA is right for you. Do not take INLYTA if you are allergic to axitinib or any of the other ingredients in INLYTA tablets. Caution is needed if you have or ever have had high blood pressure, bleeding, blood clots, problems with your thyroid, heart, brain, digestive system, blood vessels, kidneys or liver, are pregnant or planning to become pregnant or are breastfeeding. Tell your doctor if you are taking any other medicines.

Common side effects include diarrhoea, high blood pressure, tiredness, loss of appetite, nausea (feeling sick), hoarse or raspy voice, tingling or rash on palms of hands or soles of feet, weight loss, vomiting, feeling weak, constipation, thyroid problems, shortness of breath, cough, mouth ulcers, sore mouth, headache, pain in joints or extremities. If symptoms continue or you have side effects, see your doctor. You will need to pay for this medicine and normal doctor's fees apply. Contains 1 mg or 5 mg of axitinib. Further information on INLYTA is available from www.medsafe.govt.nz or Pfizer New Zealand Ltd, Auckland, www.pfizer.co.nz Ph. 0800 736 363.

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References:

INLYTA (axitinib) Consumer Medicine Information.

Pfizer New Zealand Ltd, Auckland

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