

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{PR}INLYTA[®]

axitinib tablets

This Patient Medication Information is written for the person who will be taking **INLYTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **INLYTA**, talk to a healthcare professional.

Serious warnings and precautions box

INLYTA should be prescribed and managed by a healthcare professional experienced in the use of cancer drugs.

Possible serious side effects with INLYTA include:

- high blood pressure. High blood pressure can be sudden and severe.
- blood clots in the vein or arteries that may lead to death.
- Bleeding. This includes the brain, respiratory and gastrointestinal tract.
- gastrointestinal perforation (a tear in the stomach or intestine wall) or fistula (abnormal connection between 2 parts of your body) that may result in death.
- reversible posterior leukoencephalopathy syndrome, symptoms include headache, confusion, seizures, and visual loss.
- heart problems that may lead to death.

What INLYTA is used for:

INLYTA is used to treat adults with:

- metastatic (cancer spread to other parts of the body) renal cell carcinoma (kidney cancer) who have had other treatments (sunitinib or a cytokine). INLYTA is used when sunitinib or cytokine treatments no longer work.
- advanced and metastatic renal cell carcinoma in combination with another drug called pembrolizumab. INLYTA, in combination with pembrolizumab, is used in adults who have not received any previous treatments.

How INLYTA works:

INLYTA specifically targets the action of certain enzymes called tyrosine kinases. Tyrosine kinases are involved in cell growth and the development of new blood vessels. By blocking its action, INLYTA

prevents growth of blood vessels from surrounding tissue to a solid tumour, and prevents the growth of cancer cells.

The ingredients in INLYTA are:

Medicinal ingredient: axitinib

Non-medicinal ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate microcrystalline cellulose and Opadry® II Red. The Opadry® II Red film coating contains lactose monohydrate, HPMC 2910/Hypromellose 15cP, titanium dioxide, triacetin (glycerol triacetate), and red iron oxide.

INLYTA comes in the following dosage form(s):

tablets; 1 mg and 5 mg.

Do not use INLYTA if:

- you are allergic (hypersensitive) to axitinib or any of the other ingredients of INLYTA, listed under “The ingredients in INLYTA are:”

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take INLYTA. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure and its complications, including separation of the layers of the arterial wall (artery dissection).
- have thyroid gland problems.
- have untreated brain metastasis (cancer spread to the brain).
- are at risk of developing blood clots or have had recent problems with blood clots in your veins or arteries. This can lead to stroke, heart attack, embolism (blood clot in lungs), or thrombosis (blood clot in legs).
- have bleeding problems.
- have an unhealed wound following surgery or if you have surgery scheduled.
- have liver or kidney problems.
- have any gastrointestinal disorders.
- have any neurological disorders (e.g., headache, seizure, weakness, confusion, blindness and other visual problems).
- have heart problems such as:
 - chest pain, had a surgical procedure to treat severe artery blockages, congestive heart failure
 - low heart rate, at risk of developing a low heart rate or are taking medications that lower your heart rate.
- have a rare hereditary problem of lactose intolerance.

Other warnings you should know about:

Fertility: Taking INLYTA may impact your fertility. This may affect the ability to have children.

Pregnancy and breastfeeding:**Female patients:**

- Avoid becoming pregnant while taking INLYTA. INLYTA can harm your unborn baby. If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- Your healthcare professional will complete a pregnancy test before you start your treatment with INLYTA.
- Use effective methods of birth control if you are able to get pregnant. Speak to your healthcare professional about birth control methods that are right for you.
- It is not known if INLYTA passes into breast milk. Do not breastfeed during treatment with INLYTA. Talk to your healthcare professional about the best way to feed your baby during this time.

Male patients: Use effective birth control if you have a female partner who is able to get pregnant.

Driving and using machines: INLYTA can cause you to feel dizzy and tired. Before you do tasks which may require special attention, wait until you know how you respond to INLYTA.

Check-ups and testing: You will have regular visits with a healthcare professional before and during your treatment with INLYTA. At these visits, your healthcare professional may:

- check your blood pressure.
- check the condition of your heart.
- monitor for gastrointestinal perforation or fistula.
- do blood tests. The results of these tests will tell your healthcare professional how INLYTA is affecting your blood, thyroid and liver.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following may also interact with INLYTA:

- Medicines that treat fungal infections, such as itraconazole, ketoconazole, voriconazole
- Medicines that treat bacterial infections (antibiotics), such as clarithromycin, telithromycin, nafcillin
- Medicines that treat HIV or AIDS, such as atazanavir, indinavir, nelfinavir, ritonavir, saquinavir, efavirenz, etravirine
- Medicines that treat depression, such as nefazodone
- Medicines that treat tuberculosis, such as rifampin, rifabutin, rifapentin
- Steroids, such as dexamethasone
- Medicines used to treat epilepsy or fits, such as phenytoin, carbamazepine, phenobarbital
- Medicines used to treat high blood pressure, such as bosentan
- Stimulants, such as modafinil
- Proton pump inhibitors
- H2-receptor antagonists
- Antacids, such as rabeprazole. Avoid taking antacids 2 hours before and 2 hours after taking INLYTA.
- St. John's wort

Do not drink grapefruit juice or eat grapefruit as they may change the amount of INLYTA in your body.

How to take INLYTA:

- Take INLYTA exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.
- Swallow the tablet whole with a glass of water. Take with or without food.
- Do not drink grapefruit juice or eat grapefruit as they may change the amount of INLYTA in your body.
- You may take INLYTA alone or with pembrolizumab. If you take INLYTA with pembrolizumab, it is important that you read the Patient Medication Information for pembrolizumab.

Usual dose:

starting dose: 5 mg twice a day.

maximum dose: 10 mg twice a day.

Overdose:

If you think you, or a person you are caring for, have taken too much INLYTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you vomit or miss a dose of INLYTA, don't take an additional dose. Take the next dose at the usual time.

Possible side effects from using INLYTA:

These are not all the possible side effects you may have when taking INLYTA. If you experience any side effects not listed here, tell your healthcare professional.

- back pain
- diarrhea
- nausea
- vomiting
- constipation
- soreness of the mouth, tongue, or throat
- abdominal and upper stomach pain
- upset stomach
- tiredness or feeling weak
- hoarseness (disorder of the voice)
- decreased appetite

- decreased weight
- joint pain
- pain in extremity
- headache
- taste disturbance
- cough
- breathlessness
- dry skin
- itchy skin
- hair loss
- redness of skin
- dizziness
- muscle pain
- dehydration
- hemorrhoids
- ringing in the ears
- painful tongue

INLYTA can cause abnormal physical exams, blood and urine test results. Your healthcare professional will decide when to perform the tests, exams and will interpret the results. They will tell you if there are any abnormalities in your tests that might need treatment.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
High levels of liver enzymes or bilirubin in the blood: nausea, vomiting, weight loss, fatigue, yellowing of the skin or eyes, dark urine, itching.		X	
Proteinuria (too much protein in your urine): swelling of the hands, feet, face		X	
Mucosal inflammation (inflammation of the mucosa, the mucous membranes that line your mouth and your entire gastrointestinal tract): swollen mouth and gums, dry mouth, extra thick saliva, mouth ulcers, difficulty swallowing, abdominal pain, blood or mucus in stool	X		
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
lips and skin, racing pulse or heart palpitations			
Hemorrhage (bleeding problems): nosebleed, blood in urine, rectal bleeding, coughing up blood, dizziness, weakness		X	
Hyperthyroidism (high thyroid hormone): anxiety or nervousness, weight loss, frequent and loose bowel movements, breathlessness, feeling hot and possibly feelings of having rapid, fluttering or pounding heart		X	
Palmar-plantar erythrodysesthesia syndrome (Hand-Foot syndrome): red or swollen palms, thick calluses and blisters of the hands and soles of the feet, tingling or burning, tightness of the skin		X	
Common			
Retinal-vein occlusion (blockage of the veins carrying blood away from the retina): blurry vision or vision loss, dark spots or lines in your field of vision, pain or pressure in your eye.			X
Renal failure (kidney problems): confusion, itchiness or rashes, puffiness in your face and hands, swelling in your feet or ankles, urinating less or not at all, weight gain			X
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			X
Polycythemia (high levels of red blood cells): headaches, confusion, trouble sleeping, weakness and fatigue		X	
Anemia (low levels of red blood cells): fatigue, having pale skin, shortness of breath, loss of energy or weakness		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Cardiomyopathy (Disease of heart muscles): shortness of breath, fatigue, and swollen feet, ankles, legs and abdomen		X	
Uncommon			
Retinal artery occlusion (blood flow to the eye's retina is blocked): sudden, painless vision loss, blind spots in your vision, loss of your side vision, things may look wavy or out of shape			X
Reversible Posterior Leukoencephalopathy Syndrome (a rare neurological disorder): headaches, seizures, confusion, speech and visual loss, high blood pressure			X
Hypothyroidism (decreased thyroid gland function): fatigue, constipation, dry skin, weight gain		X	
Thromboembolism (blood clot in a vein or artery): pain or tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness		X	
Pulmonary Embolism (blood clot in the lungs): sharp chest pain, coughing up blood, sudden shortness of breath			X
Gastrointestinal perforation (tear in intestinal wall): abdominal pain or cramping, bloating or a swollen abdomen, fever, chills, nausea, vomiting, pain/tenderness when touching abdomen			X
Myasthenia gravis (autoimmune neuromuscular disorder): muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing		X	
Myocarditis (inflammation of the heart muscle and lining around the heart): abnormal heartbeat, chest pain that may resemble a heart attack, fatigue, fever and other signs of infection including headache, muscle aches, sore throat, diarrhea, or rashes, joint pain or swelling, leg swelling, shortness of breath		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Flesh-Eating Disease (bacterial infection of the skin): a red, warm, or swollen area of skin that spreads quickly, severe pain, including pain beyond the area of the skin that is red, warm, or swollen, fever.			X
Pneumonitis (inflammation of the lung tissue): shortness of breath, cough, fatigue, loss of appetite, unintentional weight loss			X
Very rare			
Artery Dissection (tear in a wall of a heart artery): sudden severe pain in the back, chest or abdomen			X
Artery Aneurysm (a bulge in the wall of any artery including in the chest, arms, legs, heart, and brain): cough, coughing up blood, strong pain high in your neck or in your back when you didn't hurt yourself, problems swallowing, hoarse voice, unusual pulsing in your chest or abdomen			X
Unknown			
Wound complication: a wound that does not heal		X	
Pancreatitis (inflammation of pancreas): pain in the stomach caused by inflammation of the pancreas		X	

Some of these side effects may occur when taking INLYTA or when taking INLYTA with pembrolizumab. If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store INLYTA tablets at room temperature (15 - 30°C) in the original package.

Do not use after the expiry date (EXP) shown on the outer pack and label.

Do not use any pack that is damaged or shows signs of tampering.

As with all medicines, INLYTA should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicines no longer required. These measures will help to protect the environment.

Keep out of reach and sight of children.

If you want more information about INLYTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca; or by calling the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information).

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