

PART III: CONSUMER INFORMATION**PRINLYTA®
(axitinib tablets)**

This leaflet is part III of a three-part "Product Monograph" published when INLYTA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INLYTA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

INLYTA is used in the treatment of adult patients with metastatic (the spread of cancer to other parts of the body) kidney cancer (Renal Cell Carcinoma or RCC) who have had other treatments.

INLYTA is used with another drug called pembrolizumab to treat adults with kidney cancer (Renal Cell Carcinoma or RCC). It is used when the kidney cancer has spread to other parts of the body and has not been treated before.

What it does:

INLYTA specifically targets the activity of certain enzymes called tyrosine kinases that play a major role in transmitting the chemical signals required for critical cellular processes. INLYTA prevents growth of blood vessels from surrounding tissue to a solid tumour, and prevents the growth of cancer cells.

When it should not be used:

Do not take INLYTA:

- If you are allergic (hypersensitive) to axitinib or any of the other ingredients of INLYTA, listed under "**What the nonmedicinal ingredients are:**"

What the medicinal ingredient is:

axitinib

What the nonmedicinal ingredients are:

The nonmedicinal ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate 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.

What dosage forms it comes in:

INLYTA is available as oral tablets containing 1 mg, 3mg, 5 mg, or 7 mg of axitinib.

INLYTA 5 mg tablets are film-coated, triangular shaped tablets debossed with "Pfizer" on one side and "5 XNB" on the other side.

INLYTA 1 mg tablets are film-coated, oval shaped tablets debossed with "Pfizer" on one side and "1 XNB" on the other side.

INLYTA 3 mg tablets are film-coated, round shaped tablets debossed with "Pfizer" on one side and "3 XNB" on the other side.

INLYTA 7 mg tablets are film-coated, diamond shaped tablets debossed with "Pfizer" on one side and "7 XNB" on the other side.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

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

INLYTA has not been studied in patients with severely reduced liver function (severe hepatic impairment).

Possible serious side effects with INLYTA include:

- high blood pressure and high blood pressure crisis
- blood clots in the vein or the artery
- bleeding (in the brain, respiratory and gastrointestinal tract)
- gastrointestinal perforation (a tear in the stomach or intestine wall) that may result in death
- reversible posterior leukoencephalopathy syndrome, symptoms include headache, confusion, seizures, and visual loss.
- heart problems that may lead to death.

BEFORE you use INLYTA talk to your doctor or pharmacist:

- If you have high blood pressure and its complications, including separation of the layers of the arterial wall (Artery Dissection).
- If you have thyroid gland problems.
- If you have had a recent problem with blood clots in your veins or arteries (types of blood vessels) including stroke, heart attack, embolism, or thrombosis.
- If you have bleeding problems.
- If you have an unhealed wound following surgery or if you have surgery scheduled.
- If you have liver or kidney problems.
- If you have any gastrointestinal disorders.
- If you have any neurological disorders.
- If you have heart problems.
- If you are pregnant or planning to become pregnant. INLYTA may affect male and female fertility.
- If you are breast-feeding or planning to breast-feed. It is not known if INLYTA passes into your breast milk. You and your doctor should decide if you will take INLYTA or breast-feed. You should not do both.
- If you have a rare hereditary problem of lactose intolerance.

Use in children (under 18 years):

INLYTA is not recommended for use in children since it has not been studied in children under 18 years of age.

Contraception:

- INLYTA may cause birth defects.
- Women should not get pregnant and should not plan to get pregnant during treatment with INLYTA.
- Men and women should use effective birth control during treatment with INLYTA. Talk with your doctor about effective birth control methods.
- Call your doctor right away if you become pregnant during treatment with INLYTA.

INTERACTIONS WITH THIS MEDICATION

Taking other medicines:

Tell your doctor if you are taking other drugs, including prescription and non-prescription, vitamins, and herbal products. INLYTA and certain other medicines can interact with each other and cause serious side effects.

Especially tell your doctor if you take:

- Dexamethasone (a steroid).
- Medicine for: asthma, tuberculosis (TB), seizures (epilepsy), bacterial infections (antibiotics), fungal infections (antifungals), depression, or HIV (AIDS).
- Herbal medicines (such as St. John’s wort).
- Antacids, such as rabeprazole, which should be avoided 2 hours before and 2 hours after taking INLYTA.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine. Do not take other medicines with INLYTA until you have talked with your doctor.

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

PROPER USE OF THIS MEDICATION

Usual dose:

- Take INLYTA exactly as prescribed by your doctor.
- Usual Starting Dose: 5 mg taken by mouth twice a day with or without food.
- Maximum dose: 10 mg twice daily.
- Swallow the tablet whole with a glass of water.
- 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. To find this information:
 - Go online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>
 - Contact your healthcare professional.

Overdose:

If you think you may have accidentally taken too many INLYTA tablets, immediately contact your doctor, or poison control centre, or go to the emergency room of the nearest hospital even if there are no 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. Call your doctor right away if you take too much INLYTA.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

INLYTA may cause the following serious side effects:

- High blood pressure
- Decreased thyroid function (hypothyroidism)
- Increased bleeding problem
- Blood clot in the veins, arteries, or lungs
- Tear in the intestinal wall (perforation of the bowel)

Very common side effects (these are likely to affect more than or equal to 1 in every 10 people):

- decreased thyroid gland function (hypothyroidism) with symptoms such as fatigue, constipation, dry skin, weight gain
- diarrhea (frequent or loose bowel movements)
- nausea
- vomiting
- constipation
- soreness of the mouth, tongue, or throat
- abdominal pain
- upset stomach
- tiredness or feeling weak
- hoarseness (disorder of the voice)
- decreased appetite
- decreased weight
- joint pain
- pain in extremity
- headache
- taste disturbance
- protein in urine
- cough
- breathlessness
- rash, redness, itching or peeling of your skin (hand-foot syndrome)
- dry skin
- itchy skin
- hair loss
- redness of skin
- high blood pressure
- bleeding problems (nosebleed, blood in urine, rectal bleeding, coughing up blood)

Common side effects (these are likely to affect more than or equal to 1 but less than 10 in every 100 people):

- dizziness

- upper stomach pain
- muscle pain
- dehydration
- decreased amount of red blood cells in the blood
- hemorrhoids
- ringing in the ears
- increase in lipase (an enzyme from the pancreas)
- blood clot in the lung
- formation of blood clot in deep vein
- some vascular disorders of the retina
- increased red blood cells in the blood
- transient stroke-like episodes
- increased thyroid gland function (hyperthyroidism) with symptoms such as rapid weight loss, sweating, faster heartbeat
- excess bilirubin in blood with symptoms such as yellow coloring of the skin
- painful tongue
- kidney failure
- heart problems

Uncommon side effects (these are likely to affect more than or equal to 0.1 but less than 1 in every 100 people):

- severe and rapid increase in blood pressure (hypertensive crisis)
- loss of monocular vision (retinal artery occlusion)
- a neurological disorder called reversible posterior leukoencephalopathy syndrome with symptoms such as headache, seizures, lethargy, confusion, blindness and other visual disturbances

The most common side effects when INLYTA is given in combination with pembrolizumab are:

- diarrhea;
- nausea;
- inflammation of the moist, inner lining of the body, like the mouth, nose, lungs, stomach;
- feeling unusually tired or weak;
- fatigue;
- increase in liver enzyme levels;
- decreased appetite;
- joint pain;
- protein in urine;
- voice change;
- itching;
- rash;
- high blood pressure.

Tell your doctor if you have any side effects that bother you or that do not go away. These are not all the side effects with INLYTA. Ask your doctor or pharmacist for more information.

INLYTA can cause abnormal exam, blood and urine test results. Your doctor will do some tests before, during and after your

treatment. The doctor will interpret the results. They will tell you if there are any abnormalities in your tests that might need treatment.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Common			
high blood pressure		√	
bleeding problems (nosebleed, blood in urine, rectal bleeding, coughing up blood)		√	
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		√	
Palmar-plantar erythrodysesthesia syndrome (also called 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		√	
Common			
Heart problems (cardiomyopathy) with symptoms such as shortness of breath, fatigue, and swollen feet, ankles, legs and abdomen		√	
Uncommon			
decreased thyroid gland function (hypothyroidism) with symptoms such as fatigue, constipation, dry skin, weight gain		√	
problem with blood clots in your veins or arteries (types of blood vessels)		√	
perforation of the bowel (tear in your intestinal wall)		√	
*Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing		√	

<p>*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</p>		√	
<p>*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.</p>		√	
<p>*Pneumonitis (inflammation of the lung tissue): shortness of breath, cough, fatigue, loss of appetite, unintentional weight loss</p>		√	
<p>Very rare</p>			
<p>Artery Dissection (sudden severe pain in the back, chest or abdomen)</p>		√	
<p>Artery Aneurysm (a bulge in the wall of any artery including in the chest, arms, legs, heart, and brain): symptoms will differ by the site. They can be 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.</p>		√	

***Serious Side Effects linked to the use of INLYTA with pembrolizumab.**

This is not a complete list of side effects. For any unexpected effects while taking INLYTA, contact your doctor or pharmacist.

HOW TO STORE IT

- Store INLYTA tablets at a controlled room temperature of 25°C (excursions permitted to 15 - 30°C).
- Store 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.
- Keep INLYTA, and all other medicines, out of the reach and sight of children.
- 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be found at: www.pfizer.ca or can be obtained by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 (Medical Information)

This leaflet was prepared by Pfizer Canada ULC.

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