**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

**INLYTA® 1 mg film-coated tablets**

**INLYTA® 3 mg film-coated tablets**

**INLYTA® 5 mg film-coated tablets**

**INLYTA® 7 mg film-coated tablets**

**Axitinib**

**Contains sugar**

Each INLYTA 1 mg film-coated tablet contains 33,60 mg lactose monohydrate

Each INLYTA 3 mg film-coated tablet contains 35,28 mg lactose monohydrate

Each INLYTA 5 mg film-coated tablet contains 58,8 mg lactose monohydrate

Each INLYTA 7 mg film-coated tablet contains 82,32 mg lactose monohydrate

**Read all of this leaflet carefully before you start taking INLYTA**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- INLYTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

## 1. What INLYTA is and what it is used for

INLYTA is indicated for the treatment of advanced kidney cancer in adults, after previous systemic therapy (e.g. chemotherapy) and removal of the involved kidney has not worked.

## 2. What you need to know before you take INLYTA

**Do not take INLYTA:**

- If you are hypersensitive (allergic) to axitinib or any of the other ingredients of INLYTA (listed in section 6).
- If you are pregnant or are planning to have a baby.
- If you are breastfeeding your baby (see Pregnancy and breastfeeding).
- If you are under the age of 18 years.
- If you have experienced recent gastrointestinal bleeding (in the stomach or intestines).
- Evidence of untreated cancer (metastases) that has spread into your brain.
- If you have severe impairment of liver function.
- If you have had a recent problem with blood clots in your veins and arteries, including heart attack and stroke within the last 6 - 12 months.
- If you suffer from uncontrolled high blood pressure.
- If you suffer from uncontrolled, poor heart function.
- If you suffer from an uncontrolled under-active thyroid gland.
- If you suffer from a condition called Posterior reversible encephalopathy syndrome (PRES) which is characterised by headache, confusion, seizures and visual loss.
- If you have a tendency to bleed.
- If you have a recent history of a tear/hole in your stomach or bowel (gastrointestinal perforation) and/or fistulae (tube like tracts between organs).
- Unhealed surgery or trauma wounds.

**Warnings and precautions**

**Take special care with INLYTA:**

- **If during treatment with INLYTA, you experience symptoms such as excessive tiredness, swelling of the abdomen, legs or ankles, shortness of breath, or protruding neck veins.** INLYTA may increase the risk of developing heart failure events. Your doctor should monitor for signs or symptoms of heart failure events periodically throughout treatment with INLYTA.
- **If you have high blood pressure.** INLYTA can raise your blood pressure. It is important to check your blood pressure before you take this medicine, and regularly while you are taking it. If you have high blood pressure (hypertension) you may be treated with medicines to reduce the blood pressure. Your doctor should make sure that your blood pressure is under control before starting INLYTA treatment, and while on treatment with this medicine.
- **If you have thyroid gland problems.** INLYTA can cause thyroid gland problems. Tell your doctor if you get tired more easily, generally feel colder than other people, or your voice deepens whilst taking this medicine. Your thyroid function should be checked before you take INLYTA and regularly while you are taking it. If your thyroid gland is not producing enough thyroid hormone before, or while on treatment with this medicine, you should be treated with thyroid hormone replacement.
- **If you have had a recent problem with blood clots in your veins and arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.** Get emergency help right away and call your doctor if you get symptoms such as chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, numbness or weakness on one side of your body, trouble talking, headache, vision changes, or dizziness while on treatment with this medicine.
- **If you suffer from bleeding problems.** INLYTA may increase your chance of bleeding. Tell your doctor if you have any bleeding (such as nosebleeds, blood in urine or faeces), coughing up of blood or bloody sputum while on treatment with INLYTA.
- **If during treatment with INLYTA you get severe stomach (abdominal) pain or stomach pain that does not go away.** INLYTA may increase the risk of developing a hole in your stomach or intestine or formation of fistula (abnormal tube-like passage from one normal body cavity to another body cavity or the skin). Tell your doctor if you have severe abdominal pain while on treatment with this medicine.

- **If you are going to have an operation or if you have an unhealed wound.** Your doctor should stop INLYTA at least 24 hours before your operation as it may affect wound healing. Your treatment with this medicine should be restarted when the wound has adequately healed.
- **If during treatment with INLYTA, you get symptoms such as headache, confusion, seizures (fits), or changes in vision with or without high blood pressure.** Get emergency help right away and call your doctor. This could be a rare neurological side effect named reversible posterior encephalopathy syndrome.
- **If you have liver problems.** Your doctor should do blood tests to check your liver function before and during treatment with INLYTA.

**Other medicines and INLYTA**

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines.)

The medicines listed below **should be avoided** during your treatment with INLYTA. If you are taking any of them, tell your doctor, pharmacist or nurse. Your doctor may change the dose of these medicines, change the dose of INLYTA, or switch you to a different medicine. The medicines listed in this leaflet may not be the only ones that could interact with INLYTA.

The following medicines may increase the risk of side effects with INLYTA:

- Ketoconazole or itraconazole (used to treat fungal infections).
- Clarithromycin or telithromycin (antibiotics used to treat bacterial infections).
- Atazanavir, indinavir, nelfinavir, ritonavir or saquinavir (used to treat HIV infections/AIDS).
- Theophylline (used to treat asthma or other lung diseases).

The following medicines may reduce the effectiveness of INLYTA:

- Rifampicin, rifabutin or rifapentin (used to treat tuberculosis [TB]).
- Dexamethasone (a steroid medicine prescribed for many different conditions, including serious illnesses).

- Phenytoin, carbamazepine or phenobarbitone (anti-epileptics used to stop seizures or fits).
- St. John's wort (*Hypericum perforatum*) (a herbal product used for depression).

**INLYTA with food and drink**

You can take INLYTA either with or without food.

Do not take INLYTA with grapefruit or grapefruit juice, as it may increase the chance of side effects.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

- INLYTA could harm an unborn baby. Do not take INLYTA during pregnancy.
- Talk to your doctor before taking INLYTA if you might become pregnant. Use a reliable method of contraception while you are taking INLYTA and up to 1 week after the last dose, to prevent pregnancy.
- Do not breastfeed your baby during treatment with INLYTA.
- INLYTA has the potential to impair reproductive function and fertility in men and women.

**Consider preserving your sperm/egg before starting treatment with INLYTA.**

**Driving and using machines**

- INLYTA may make you feel dizzy, drowsy or sleepy.
- Do not drive because INLYTA could interfere with your ability to drive safely.
- Do not operate any tools or machines.

It is not always possible to predict to what extent INLYTA may interfere with your daily activities. You should not engage in the above activities until you know how INLYTA affects you.

**INLYTA contains lactose (milk sugar)**

INLYTA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance (e.g. galactocaemia) should not take INLYTA.

## 3. How to take INLYTA

Do not share medicines prescribed for you with any other person.

Always take INLYTA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 5 mg twice a day. Your doctor may subsequently increase or decrease your dose depending on how you tolerate treatment with INLYTA.

Swallow the tablets whole with water, with or without food. Take the INLYTA doses approximately 12 hours apart.

Your doctor will tell you how long your treatment with INLYTA will last. Do not stop treatment early.

If you have the impression that the effect of INLYTA is too strong or too weak, tell your doctor or pharmacist.

**Use in children and adolescents**

INLYTA is not recommended for people under 18 years of age. This medicine has not been studied in children and adolescents.

**If you take more INLYTA than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take INLYTA**

Do not take a double dose to make up for forgotten individual doses.

## 4. Possible side effects

INLYTA can have side effects.

Not all side effects reported for INLYTA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INLYTA, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- **Blood clots in your veins and arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.** Get emergency help right away and call your doctor if you get symptoms such as chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, numbness or weakness on one side of your body, trouble talking, headache, vision changes, or dizziness.
- **Bleeding.** Tell your doctor right away if you have any of these symptoms or a serious bleeding problem during treatment with INLYTA: black tarry stools, coughing up of blood or bloody sputum, or change in your mental status.
- **Hole in stomach or intestine or formation of fistula (abnormal tube-like passage from one normal body cavity to another body cavity or the skin).** Tell your doctor if you have severe abdominal pain.
- **Severe increase in blood pressure (hypertensive crisis).** Tell your doctor if you have a very high blood pressure, severe headache, or severe chest pain.
- **Reversible swelling of the brain (posterior reversible encephalopathy syndrome).** Get emergency help right away and call your doctor if you get symptoms such as headache, confusion, seizures (fits), or changes in vision with or without high blood pressure.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INLYTA. You may need urgent medical attention or hospitalisation.

Side effects that may be experienced with INLYTA include:

*Frequent side effects:*

- Underactive thyroid gland or hypothyroidism (may show in your blood tests)
- Loss of appetite
- Headache
- Taste disturbance or loss of taste
- High blood pressure, or increases in blood pressure
- Bleeding
- Difficulty in breathing or shortness of breath
- Cough
- Hoarseness
- Diarrhoea
- Feeling or being sick (nausea or vomiting)
- Stomach-ache
- Soreness of the mouth, tongue or throat (stomatitis)
- Constipation
- Heartburn or indigestion
- Redness and swelling of the palms of the hands or soles of the feet (hand-foot syndrome)
- Skin rash
- Dryness of the skin
- Joint pain
- Pain in hands or feet
- Protein in the urine (may show in your urine tests)
- Lack of energy
- Feeling weak or tired
- Inflammation of the mucosa (moist linings of body cavities e.g. mouth)
- Weight loss
- Anaemia (decreased number of red blood cells) which may show in your blood tests
- Increase in the number of red blood cells which may show in your blood tests
- Overactive thyroid gland or hyperthyroidism (may show in your blood tests)

- Dehydration (loss of body fluids)
- Dizziness
- Ringing/sound in the ears (tinnitus)
- Heart failure
- Blood clots in your veins and arteries
- Upper stomach-ache
- Haemorrhoids
- A burning or stinging sensation in the mouth
- Bleeding from the rectum
- Fistula (abnormal tube-like passage from one normal body cavity to another body cavity or the skin)
- Jaundice (yellow discolouration of the skin and eyes due to increased levels of bile pigments in the blood resulting from liver disease)
- Skin itching
- Redness of the skin
- Hair loss
- Muscle pain
- Changes in the levels of different chemicals/enzymes in the blood which may show in your blood tests

*Less frequent side effects:*

- Headache
- Confusion
- Seizures (fits)
- Changes in vision with or without high blood pressure due to reversible swelling of the brain (posterior reversible encephalopathy syndrome)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of INLYTA.

## 5. How to store INLYTA

Store all medicines out of reach of children.

- Store at or below 30 °C
- Store in the original package / container
- Keep the blisters in the outer carton until required for use
- Keep the bottles tightly closed
- Protect from light
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What INLYTA contains**

- The active substance is axitinib.

Each INLYTA 1 mg film-coated tablet contains 1 mg axitinib

Each INLYTA 3 mg film-coated tablet contains 3 mg axitinib

Each INLYTA 5 mg film-coated tablet contains 5 mg axitinib

Each INLYTA 7 mg film-coated tablet contains 7 mg axitinib

- The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate. The tablets contain a film coat consisting of hypromellose, titanium dioxide, lactose monohydrate, triacetin and red iron oxide.

**What INLYTA looks like and contents of the pack**

INLYTA 1 mg film-coated tablets are red, oval shaped and debossed with “Pfizer” on one side and “1 XNB” on the other. INLYTA 1 mg film-coated tablets are available in 60 mL or 120 mL white HDPE bottles containing desiccant with induction seal and child-resistant white polypropylene closures containing 60, 90 or 180 tablets respectively or cartons containing aluminium foil blisters with aluminium foil backing of 14 tablets per blister strip, in pack sizes of 28 or 56 tablets.

INLYTA 3 mg film-coated tablets are red, round shaped and debossed with “Pfizer” on one side and “3 XNB” on the other. INLYTA 3 mg film-coated tablets are available in 60 mL and 120 mL white HDPE bottles containing desiccant with induction seal and child-resistant white polypropylene closures containing 60, 90 or 180 tablets respectively or cartons containing aluminium foil blisters with aluminium foil backing of 14 tablets per blister strip, in pack sizes of 28 or 56 tablets.

INLYTA 5 mg film-coated tablets are red, triangular shaped and debossed with “Pfizer” on one side and “5 XNB” on the other. INLYTA 5 mg film-coated tablets are available in 60 mL and 180 mL white HDPE bottles containing desiccant with induction seal and child-resistant white polypropylene closures containing 60, 90 or 180 tablets respectively or cartons containing aluminium foil blisters with aluminium foil backing of 14 tablets per blister strip, in pack sizes of 28 or 56 tablets.

INLYTA 7 mg film-coated tablets are red, diamond shaped and debossed with “Pfizer” on one side and “7 XNB” on the other. INLYTA 7 mg film-coated tablets are available in 60 mL and 325 mL white HDPE bottles containing desiccant with induction seal and child-resistant white polypropylene closures containing 60, 90 or 180 tablets respectively or cartons containing aluminium foil blisters with aluminium foil backing of 14 tablets per blister strip, in pack sizes of 28 or 56 tablets.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

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