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Package Leaflet: Information for the user

Axitinib 1 mg film-coated tablets

Axitinib 5 mg film-coated tablets

INLYTA®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Inlyta (Axitinib) is and what it is used for

Inlyta (Axitinib) is a medicine containing the active substance axitinib. Inlyta (Axitinib) reduces the blood supply to the tumour and slows down the growth of cancer.

Inlyta (Axitinib) is indicated for the treatment of advanced kidney cancer (advanced renal cell carcinoma/RCC) in patients, when another medicine (systemic therapy) is no longer stopping disease from progressing.

If you have any questions about how this medicine works or why this medicine has been prescribed for you, ask your doctor.

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2. What you need to know before you take Inlyta (Axitinib)

Do not take Inlyta (Axitinib):

If you are allergic to Inlyta (Axitinib) or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice.

Warnings and precautions

Talk to your doctor or nurse before taking Inlyta (Axitinib)

- **If you have high blood pressure.**
Inlyta (Axitinib) 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 (Axitinib) treatment, and while on treatment with this medicine.
- **If you have thyroid gland problems.**
Inlyta (Axitinib) can cause thyroid gland problems. Tell your doctor if you get tired more easily, have gained or lost considerable weight recently, have increased appetite or sweating, generally feel colder or hotter than other people, or your voice deepens whilst taking this medicine. Your thyroid function should be checked before you take Inlyta (Axitinib) 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 or blood clot in the lung vessels which causes chest pain and breathlessness, blood clot in the leg which causes pain, swelling or redness, when a blood clot blocks in the veins of eye. Increases in haemoglobin or haematocrit, reflective of increases in red blood cell mass, may occur during treatment with Inlyta (Axitinib).**
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 (Axitinib) may increase your chance of bleeding. Tell your doctor if you have any bleeding, coughing up of blood or bloody sputum while on treatment with this medicine.
- **If you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall which allows blood to leak out into surrounding tissue**
- **If during treatment with this medicine you get severe stomach (abdominal) pain or stomach pain that does not go away.**
Inlyta (Axitinib) may increase the risk of developing a hole in the 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 (Axitinib) 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 this medicine, you get symptoms such as headache, confusion, seizures (fits), lethargy 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 posterior reversible encephalopathy syndrome.
 - **If you have liver problems.**
Your doctor should do blood tests to check your liver function before and during treatment with Inlyta (Axitinib).
- If you have kidney problems.**
Your doctor should do blood tests to check your kidney function before and during treatment with Inlyta (Axitinib).
- **If during treatment with this medicine, you get symptoms such as excessive tiredness, swelling of the abdomen, legs or ankles, shortness of breath, or protruding neck veins.**
Inlyta (Axitinib) 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 (Axitinib).
 - **Use in children and adolescents.**
Inlyta (Axitinib) is not recommended for people aged under 18. This medicine has not been studied in children and adolescents.
 - **If during treatment with this medicine, you get symptoms such as presence of excessive protein in your urine.**
Inlyta (Axitinib) should be discontinued if the patient develops nephrotic syndrome.
 - **No dosage adjustment is required on the basis of patient age or race.**

Other medicines and Inlyta (Axitinib)

Some medicines may affect Inlyta (Axitinib), or be affected by it. Please tell your doctor, about all the medicines you have recently taken, are currently taking, or plan to take, including medicines obtained without a prescription, vitamins, and herbal medicines. The medicines listed in this leaflet may not be the only ones that could interact with Inlyta (Axitinib).

The following medicines may increase the risk of side effects with Inlyta (Axitinib):

- ketoconazole or itraconazole;
- clarithromycin, erythromycin or telithromycin, antibiotics;
- atazanavir, indinavir, nelfinavir, ritonavir or saquinavir;
- nefazodone.

The following medicines may reduce the effectiveness of Inlyta (Axitinib):

- rifampicin, rifabutin or rifapentin;
- dexamethasone, a steroid medicine;
- phenytoin, carbamazepine or phenobarbital, anti-epileptics;

- St. John's wort (*Hypericum perforatum*).

You **should not** take these medicines during your treatment with Inlyta (Axitinib). If you are taking any of them, tell your doctor. Your doctor may change the dose of these medicines, change the dose of Inlyta (Axitinib), or switch you to a different medicine.

Inlyta (Axitinib) may increase side effects associated with theophylline, used to treat asthma or other lung diseases.

Inlyta (Axitinib) with food and drink

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

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- Inlyta (Axitinib) could harm an unborn baby or breast-fed baby.
- Do not take this medicine during pregnancy. Talk to your doctor before taking it if you are pregnant or might become pregnant.
- Use a reliable method of contraception while you are taking Inlyta (Axitinib) and up to 1 week after the last dose of this medicine, to prevent pregnancy.
- Do not breast-feed during treatment with Inlyta (Axitinib). If you are breast-feeding, your doctor should discuss with you whether to discontinue breast-feeding or discontinue Inlyta (Axitinib) treatment.
- Based on non-clinical findings, Inlyta (Axitinib) has the potential to impair reproductive function and fertility in humans

Driving and using machines

If you experience dizziness and/or feel tired while on treatment with Inlyta (Axitinib), take special care when driving or using machines.

Inlyta (Axitinib) contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Inlyta (Axitinib) contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Inlyta (Axitinib)

Always take this medicine exactly as your doctor has told you. You should check with your doctor, if you are not sure.

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

Swallow the tablets whole with a glass of water, with or without food. Take the Inlyta (Axitinib) doses approximately 12 hours apart.

If you take more Inlyta (Axitinib) than you should

If you accidentally take too many tablets or a higher dose than you need, contact a doctor for advice right away. If possible, show the doctor the pack, or this leaflet. You may require medical attention.

If you forget to take Inlyta (Axitinib)

Take your next dose at your regular time. Do not take a double dose to make up for the forgotten tablets.

If you vomit while taking Inlyta (Axitinib)

If you vomit, an additional dose should not be taken. The next prescribed dose should be taken at the usual time.

If you stop taking Inlyta (Axitinib)

If you are not able to take this medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor right away.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious. You must immediately contact your doctor if you experience any of those following serious side effects (see also section 2 “What you need to know before you take Inlyta (Axitinib)”):

- **Heart failure events.** Tell your doctor if you experience excessive tiredness, swelling of the abdomen, legs, or ankles, shortness of breath, or protruding neck veins.
- **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 (Axitinib): black tarry stools, coughing up of blood or bloody sputum, or change in your mental status.

- **Hole in the 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), lethargy or changes in vision with or without high blood pressure.

Other side effects with Inlyta (Axitinib) may include:

Very common: may affect more than 1 in 10 people

- High blood pressure, or increases in blood pressure, Haemorrhage
- Diarrhoea, feeling or being sick (nausea or vomiting), stomach ache, indigestion, soreness of the mouth, tongue or throat, constipation
- Shortness of breath, cough, hoarseness
- Lack of energy, feeling weak or tired
- Under-active thyroid gland (may show in your blood tests)
- Redness and swelling of the palms of the hands or soles of the feet (hand-foot syndrome), skin rash, dryness of the skin
- Inflammation of the mucosa
- Joint pain, pain in hands or feet
- Reduced appetite
- Protein in the urine (may show in your urine tests)
- Weight loss
- Headache, taste disturbance or loss of taste

Common: may affect up to 1 in 10 people

- Dehydration (loss of body fluids)
- Kidney failure
- Flatulence (wind), upper abdominal pain haemorrhoids, bleeding from the rectum, a burning or stinging sensation in the mouth
- Burning or pain of the tongue (glossodynia)
- Hyper-active thyroid gland (may show in your blood tests)
- Sore throat or nose and throat irritation
- Muscle pain
- Nose bleeding
- Skin itching, redness of the skin, hair loss
- Ringing/sound in the ears (tinnitus)
- Reduction in the number of red blood cells (may show in your blood tests)
- Reduction in the number of blood platelets (cells that help blood to clot) (may show in your blood tests)
- Presence of red blood cells in the urine (may show in your urine tests)
- Changes in the levels of different chemicals/enzymes/electrolytes in the blood (may show in your blood tests)
- Increase in the number of red blood cells (may show in your blood tests)

- Swelling of the abdomen, legs, or ankles, protruding neck veins, excessive tiredness, shortness of breath (signs of heart failure events)
- Fistula (abnormal tube like passage from one normal body cavity to another body cavity or the skin)
- Dizziness
- Increase in bilirubin
- Inflammation of the gall bladder
- Clot in artery and veins

Uncommon: may affect up to 1 in 100 people

- Reduction in the number of white blood cells (may show in your blood tests)
- Posterior reversible encephalopathy syndrome. PRES is a neurological disorder which can present with headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances with or without increase blood pressure

Not known: frequency cannot be estimated from the available data

- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).
- Pain in the stomach (abdomen) caused by inflammation of the pancreas.

5. How to store Inlyta (Axitinib)

Store below 30°C.

Keep this medicine out of the sight and reach of children.

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

Do not throw away any medicines via wastewater or household waste. Ask your doctor how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Inlyta (Axitinib) contains

- The active substance is Axitinib. Inlyta film-coated tablets come in different strengths.
Inlyta 1 mg: each tablet contains 1 mg Axitinib
Inlyta 5 mg: each tablet contains 5 mg Axitinib
- The other ingredients are Microcrystalline Cellulose, Lactose Monohydrate, Croscarmellose Sodium, Magnesium Stearate, Opadry II red 32K15441* and Purified water[#]

[#] Evaporates during the coating process.

* Opadry II Red 32K15441 is a branded coating mixture supplied by Colorcon and contains: HPMC2910/Hypromellose 15cP, Titanium Dioxide, Lactose Monohydrate, Triacetin (Glycerol Triacetate), Red Iron Oxide

See section 2: Inlyta (Axitinib) contains lactose.

What Inlyta (Axitinib) looks like and contents of the pack

Inlyta (Axitinib) 1 mg film-coated tablets are red oval film-coated tablet debossed with “Pfizer” on one side and “1 XNB” on the other. Inlyta (Axitinib) 1 mg is available in foil/foil blister containing 14 tablets. A blister is composed of polyamide/aluminum/polyvinyl chloride blister films with aluminum/heat seal coating lidding. Packs containing 28 ([14 tabs/blister] x [2 blisters]).

Inlyta (Axitinib) 5 mg film-coated tablets are red, triangular film-coated tablet debossed with “Pfizer” on one side and “5 XNB” on the other. Inlyta (Axitinib) 5 mg foil/foil blister containing 14 tablets. A blister is composed of polyamide/aluminum/polyvinyl chloride blister films with aluminum/heat seal coating lidding. Packs containing 28 ([14 tabs/blister] x [2 blisters]).

All strengths/ Pack sizes mentioned in this document might not be available in the market.

Imported and marketed by

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