

INLYTA[®] FILM-COATED TABLETS

Axitinib (1 mg, 5 mg)

What is in this leaflet:

1. What Inlyta is used for
2. How Inlyta works
3. Before you use Inlyta
4. How to use Inlyta
5. While you are using it
6. Side Effects
7. Storage and Disposal of Inlyta
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Inlyta is used for

Inlyta is used to treat a certain type of kidney cancer called advanced renal cell carcinoma (RCC) when another medicine (called sunitinib or a cytokine) is no longer effective.

How Inlyta works

Inlyta belongs to a group of medicines called tyrosine kinase inhibitors. It contains the active substance axitinib. It works by reducing the blood supply, slowing down tumour growth and preventing spread of the cancer.

Before you use Inlyta

- When you must not use it

Do not take Inlyta:

- If you have any allergy to any medicine containing axitinib or any of the inactive ingredients listed at the end of this leaflet
- If you have severe hypertension. Your hypertension must be managed first before starting treatment
- If you have had a recent active gastrointestinal bleed or cancer which have spread to the brain
- If you have nephrotic syndrome, which is a collection of symptoms due to kidney damage, one of which is proteinuria (presence of excess protein in urine)
- If you have severe liver impairment (classified as Child-Pugh class C)
- If you have lactose intolerance, as this product contains lactose

If you think you may be allergic ask your doctor for advice.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Pregnancy and lactation

Tell your doctor if you are pregnant or think you may be pregnant or are planning to become pregnant as Inlyta could harm an unborn baby.

Inlyta should not be taken during pregnancy unless your clinical condition requires treatment with this medicine. Your doctor will discuss the risks with you.

It is not known if Inlyta is passed into breast milk. You should not breastfeed while taking Inlyta.

- Before you start to use it

You must tell your doctor if you have or have had any of the following medical conditions before starting treatment with Inlyta:

- Heart failure events
- High blood pressure. Your blood pressure should be well-controlled with standard antihypertensive therapy.
- Inlyta may cause swelling of arteries or blood to clot in patients with or without high blood pressure. Therefore, your doctor may consider the risk before prescribing the medicine.
- Thyroid gland problems. Your doctor should monitor your thyroid function and treat it accordingly before starting Inlyta.
- High red blood cell mass. Your doctor should monitor your red blood cell count and ensure your red blood cell count is normal before starting Inlyta.
- Bleeding problems

- Gastrointestinal perforation and fistula formation (abnormal tube-like passage from one normal body cavity to another body cavity or the skin).
- You have an unhealed wound, or if you have surgery scheduled. You should not take Inlyta 24 hours before a surgery.
- Neurological disorder called as Posterior reversible encephalopathy syndrome (PRES).
- Serious kidney damage causing presence of protein in urine. Your doctor should monitor for protein in your urine before starting treatment with Inlyta.
- Liver problems. Your doctor should perform a liver function test before starting Inlyta.
- Lactose intolerance.

- Taking other medicines

Some medicines may affect Inlyta, or be affected by it. Please tell your doctor, pharmacist or nurse 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.

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, erythromycin or telithromycin, antibiotics used to treat bacterial infections
- atazanavir, indinavir, nelfinavir, ritonavir or saquinavir, medicines used to treat HIV infections/AIDS
- rifampicin, rifapentine or rifabutin, medicines used to treat tuberculosis (TB)
- nefazodone, used to treat depression
- phenytoin, carbamazepine or phenobarbital, anti-epileptic

INLYTA[®] FILM-COATED TABLETS

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medicines used to stop seizures or fits

- St. John's Wort (*Hypericum perforatum*), a herbal medicine used to treat depression and other conditions
- theophylline, used to treat asthma or other lung diseases.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Inlyta.

How to use Inlyta

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

- How much to use

Your doctor will tell you which tablets you need to take each day. For kidney cancer, the usual starting dose of Inlyta is one 5 mg tablet taken 2 times a day (for a total of 2 tablets each day). Your doctor may increase your dosage up to 10 mg twice daily based on your tolerability to Inlyta. If you are unable to tolerate the starting dose, your dosage may be reduced down to 2 mg twice daily.

- How to use it

You can take Inlyta either with or without food. Swallow the Inlyta tablets whole with a glass of water.

- When to use it

Take your medicine at about the same time each day, about approximately 12 hours apart.

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Inlyta for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

- If you forget to use it

If you forget to take Inlyta or if you vomit after taking 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 not sure what to do, ask your doctor or pharmacist.

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

- If you use too much (overdose)

Immediately telephone your doctor or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Inlyta.

Some signs of overdose are dizziness, high blood pressure, seizures associated with high blood pressure and coughing blood.

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

While you are using it

- Things you must do

- Make sure you follow your doctor's instructions and keep all appointments.
- You will need regular follow-up to make sure the treatment is working.
- Your doctor will measure your blood pressure. You will also have blood tests from time to time to

make sure the medicine is working and to check for side effects.

If you become pregnant while taking this medicine, tell your doctor immediately.

Men and women should use contraception to prevent pregnancy during and up to 1 week after treatment with Inlyta. Talk with your doctor about effective contraception.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Inlyta. Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. You should stop taking Inlyta 24 hours before your surgery. It may cause wound healing complications.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

- Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you. Do not take Inlyta to treat any other complaints unless your doctor tells you to.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- Do not drink grapefruit juice or eat grapefruit while taking Inlyta. They may change the amount of Inlyta in your body.

- Things to be careful of

Be careful while driving, operating machinery or doing jobs that require you to be alert, until you know how Inlyta affects you. Inlyta may make some people feel very tired or dizzy. If you feel light-headed, dizzy or

INLYTA[®] FILM-COATED TABLETS

Axitinib (1 mg, 5 mg)

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.

Inlyta contains sodium

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Inlyta.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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. Not everybody will experience them. Ask your doctor or pharmacist to answer any questions you may have.

Here are some very common and common side effects that may happen while being treated with Inlyta. Some of these side effects may only be detected through blood/urine tests and may not be apparent to you:

Very common: may affect more than 1 in 10 patients on Inlyta

- Under-active thyroid gland
- Decreased appetite
- Headache
- Taste disturbance or loss of taste
- High blood pressure
- Bleeding
- Cough

- Difficulty in speaking and breathing
- Diarrhoea
- Vomiting
- Nausea
- Abdominal pain
- Constipation
- Soreness of the mouth, tongue or throat
- Indigestion
- Redness and swelling of the palms of the hands or soles of the feet (hand-foot syndrome)
- Rash
- Dry skin
- Joint pain
- Pain in hands or feet
- Protein in the urine
- Fatigue
- Abnormal physical weakness or lack of energy
- Mucosal inflammation
- Weight decreased

Common: may affect more than 1 in 100, less than 1 in 10 patients on Inlyta

- Dizziness
- Low red blood cell
- Low platelets
- Thickening of the blood
- Over-active thyroid gland
- Dehydration
- Ringing/sound in the ears (tinnitus)
- Heart failure events
- Blood clots in veins and arteries
- Pain in throat
- Upper abdominal pain
- Excessive passing of gas
- Swollen veins in anus and lower rectum
- Burning or painful sensation in the tongue
- Holes in the gastrointestinal tract and fistula
- Increased levels of bilirubin in the blood
- Swelling of the gall bladder
- Severe itching of the skin
- Redness of the skin
- Hair loss
- Pain in a muscle
- High potassium level in blood
- High calcium level in blood

- Kidney failure
- Changes in the levels of different chemicals/enzymes in the blood

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Inlyta

- Storage

Keep your tablets in the pack until it is time to take them.

Keep this medicine out of the sight and reach of children

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton and on the blister foil or bottle after "EXP". The expiry date refers to the last day of the month.

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

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, do not throw away any medicines via wastewater or household waste ask your pharmacist what to do with any medicine that is left over.

Any unused product or waste material should be disposed of in accordance with local requirements.

These measures will help to protect the environment.

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Product Description

- What it looks like

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

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

Inlyta tablets are available:

- in blister packs of 28 tablets or 56 tablets
- in bottle packs of 180 tablets (1 mg) or 60 tablets (5 mg)

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

Inlyta tablets contain 1 mg or 5 mg of axitinib as the active ingredient.

- Inactive ingredients

The tablets also contain:

Core:

Microcrystalline Cellulose
Lactose Monohydrate
Croscarmellose Sodium
Magnesium Stearate

Film-coating:

Hypromellose
Titanium dioxide (E171)
Lactose monohydrate
Triacetin (E1518)
Iron oxide red (E172)

- MAL Number(s)

Inlyta 1 mg - MAL13115126AZ

Inlyta 5 mg - MAL13115127AZ

Manufacturer

Pfizer Manufacturing Deutschland
GmbH
Mooswaldallee 1,
79108 Freiburg Im Breisgau, Germany

Product Registration Holder

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