

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INLYTA?

INLYTA contains the active ingredient axitinib. INLYTA is used to treat a certain type of kidney cancer called renal cell carcinoma (RCC). For more information, see Section [1. Why am I using INLYTA?](#) in the full CMI.

2. What should I know before I use INLYTA?

Do not use if you have ever had an allergic reaction to INLYTA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use INLYTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INLYTA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use INLYTA?

- 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).

More instructions can be found in Section [4. How do I use INLYTA?](#) in the full CMI.

5. What should I know while using INLYTA?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using INLYTA. - Keep all your medical appointments while taking this medicine. - If you are of childbearing age you should use contraception to prevent pregnancy during treatment with INLYTA.
Things you should not do	- Do not stop using this medicine suddenly or lower your dose without checking with your doctor. - Do not drink grapefruit juice or eat grapefruit while taking INLYTA.
Driving or using machines	Be careful 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.
Looking after your medicine	- Keep your tablets in the pack until it is time to take them. - Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using INLYTA?](#) in the full CMI.

6. Are there any side effects?

Some common side effects may include diarrhoea; tiredness, loss of appetite; hoarseness, change in your voice; tingling or rash on palms of hands or soles of feet; weight loss; weakness; constipation; sensitive to cold, unintentional weight gain, lack of energy; soreness or burning of the mouth, tongue or throat; stomach ache, indigestion; headache, pain in hands or feet; muscle pain, joint pain; change in sense of taste, rash, dry skin, skin redness, scaly skin, itchy skin; dehydration; nose bleeding; piles, or bleeding from the back passage; hair loss; unusual urine colour; ringing or sound in the ears.

Serious side effects may include headaches, dizziness, blurred vision, nausea and vomiting (high blood pressure); foamy and frothy urine with swelling of abdomen, legs or eyes; passing little or no urine (wee), swelling in ankles or feet, confusion, nausea or vomiting, feeling breathless, tired or weak; swelling of feet or legs, leg pain, cough; chest pain or pressure, pain in your arms, back, neck or jaw; shortness of breath; numbness or weakness on one side of your body, loss of co-ordination; trouble speaking or swallowing; confusion, trouble seeing, seizures or fits; severe stomach/upper abdominal pain that may spread to your back with vomiting, fever or fast heartbeat.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using INLYTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INLYTA.**

Where to find information in this leaflet:

1. [Why am I using INLYTA?](#)
2. [What should I know before I use INLYTA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use INLYTA?](#)
5. [What should I know while using INLYTA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using INLYTA?

INLYTA contains the active ingredient axitinib. INLYTA belongs to a group of medicines called tyrosine kinase inhibitors.

INLYTA is used to treat a certain type of kidney cancer called renal cell carcinoma (RCC).

INLYTA works by reducing the blood supply to the tumour and slowing down the growth of cancer.

2. What should I know before I use INLYTA?

Warnings

Do not use INLYTA if:

- you are allergic to axitinib, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as:
 - o high blood pressure
 - o an aneurysm (abnormal balloon-like swelling in the wall of an artery)
 - o thyroid gland problems
 - o blood clots in your veins and/or arteries (types of blood vessels) or lungs
 - o stroke or heart attack
 - o bleeding problems
 - o you have an unhealed wound, or if you have surgery scheduled
 - o liver problems
 - o serious kidney problems (other than the kidney cancer for which you are being treated)
 - o lactose intolerance.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

INLYTA should not be taken during pregnancy. Your doctor will discuss the risks with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not breastfeed while taking INLYTA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with INLYTA and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INLYTA.

4. How do I use INLYTA?

How much to take

- Your doctor will tell you which tablets you need to take each day. Follow the instructions provided and use INLYTA until your doctor tells you to stop.
- 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 or decrease your dose depending on your response to INLYTA.
- Swallow the INLYTA tablets whole with a glass of water.
- You can take INLYTA either with or without food.

When to take INLYTA

- Each dose of INLYTA should be taken at the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take INLYTA

- 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.
- Continue taking your medicine for as long as your doctor prescribes it.

If you forget to take INLYTA

INLYTA should be used regularly at the same time each day.

If you miss your dose at the usual time, take your next dose at your regular time.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much INLYTA

If you think that you have taken too much INLYTA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using INLYTA?

Things you should do

Make sure you follow your doctor's instructions and keep all appointments.

During treatment with INLYTA, your doctor will perform regular tests to check for and monitor:

- blood pressure
- heart disease
- stomach and bowel problems
- kidney disease
- thyroid levels
- red blood cell count
- liver enzyme levels.

Regular follow up and blood tests are done to make sure the medicine is working and to check for side effects.

Men and women should use contraception to prevent pregnancy during treatment with INLYTA. Talk with your doctor about effective contraception.

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using INLYTA.

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 affect other medicines used during surgery.

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 should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not take INLYTA to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how INLYTA affects you.

INLYTA may make some people feel very tired or dizzy.

If you feel light-headed, dizzy or 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.

Drinking alcohol

No information is available.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- If you take the tablets out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Circulatory system issues: • high blood pressure • nose bleeding Gastrointestinal issues: • diarrhoea • nausea (feeling sick) or vomiting • constipation • soreness or burning of the mouth, tongue or throat • stomach ache, indigestion • piles, or bleeding from the back passage Skin related issues: • tingling or rash on palms of hands or soles of feet • rash, dry skin, skin redness, scaly skin, itchy skin • hair loss Respiratory issues: • hoarseness, change in your voice • shortness of breath, cough Ear issues: • ringing or sound in the ears Thyroid issues: • low thyroid hormone levels, symptoms include being more	Speak to your doctor if you have any of these less serious side effects and they worry you.

Common side effects	What to do
sensitive to cold, unintentional weight gain and lack of energy Pain issues: • pain in hands or feet • muscle pain, joint pain General disorders: • tiredness • loss of appetite • weight loss • weakness • headache • change in sense of taste • dizziness • dehydration	

Serious side effects

Serious side effects	What to do
• high blood pressure, symptoms may include headaches, dizziness, blurred vision, nausea and vomiting • foamy and frothy urine with swelling of abdomen, legs or eyes • passing little or no urine (wee), swelling in ankles or feet, confusion, nausea or vomiting, feeling breathless, tired or weak • swelling of feet or legs, leg pain, cough chest pain or pressure, pain in your arms, back, neck or jaw; shortness of breath • numbness or weakness on one side of your body, loss of co-ordination • trouble speaking or swallowing • headache, confusion, trouble seeing, seizures or fits • severe stomach/upper abdominal pain that may spread to your back with vomiting, fever or fast heartbeat	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INLYTA contains

Active ingredient (main ingredient)	Axitinib
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Croscarmellose sodium Magnesium stearate Triacetin HPMC 2910/Hypromellose 15cP Titanium dioxide (E171) Iron oxide red CI77491 (E172)
Potential allergens	INLYTA contains sugars (as lactose)

Do not take this medicine if you are allergic to any of these ingredients.

INLYTA does not contain sucrose, gluten, tartrazine or any other azo dyes.

What INLYTA 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 (2 blister cards of 14 tablets each).

Australian registration numbers

1 mg tablets: AUST R 184856

5 mg tablets: AUST R 184859

Who distributes INLYTA

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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