

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 12/2021

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Inlyta tablets 5mg

Active ingredient: Axitinib

Dosage form: red tablet, major axis: 7.7 mm, thickness: 3.8 mm

Print on wrapping: (Face) インライタ 5mg, Pfizer 5XNB, (Back) インライタ 5, Inlyta



Effects of this medicine

This medicine has an anti-tumor effect inhibiting angiogenesis and suppressing the tumor cell growth and metastasis by selectively inhibiting vascular endothelial growth factor receptors (VEGFR-1, -2 and -3).

It is usually used to treat radically unresectable or metastatic renal cell carcinoma.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.
- If you are pregnant, breastfeeding or possibly pregnant.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults, take 1 tablet (5 mg of the active ingredient) at a time, twice a day. The dosage may be adjusted according to the condition. However, the daily dosage is up to 2 tablets (10 mg) at a time, twice a day. Strictly follow the instructions.
- If you miss a dose, take the missed dose by 3 hours before the next dose or skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Avoid taking any food containing St. John's wort (a kind of herb), because the effect of the medicine may be decreased.
- Avoid drinking grapefruit juice, because it may intensify the therapeutic effects of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, hypertension, fatigue, hand-foot syndrome (pain, redness, swelling, skin peel, blisters, etc., in the palm and sole), dysphonia, nausea, decreased appetite, hypothyroidism (intolerance to cold, swollen face, malaise, slow in conversation or in motion, etc.), stomatitis, rash, mucosal inflammation, decreased weight, vomiting, asthenia, taste abnormality, itching, joint pain and headache. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- headache, dizziness, sudden elevation of blood pressure [hypertension, high blood pressure crisis]
- decreased sweating, bradycardia, dry skin, sweating, tachycardia [thyroid dysfunction]
- nose bleeding, bloody urine, black stool [bleeding]
- severe abdominal pain, melena, vomiting of blood [perforation of the digestive tract, fistula formation]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, seek advice of your pharmacy or medical institution about proper disposal of them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.