

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

Internal

Revised: 06/2020

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: Xtandi Tablets 80 mg

Active ingredient: Enzalutamide

Dosage form: yellow tablet, major axis: approx. 17.2 mm, minor axis: approx. 9.1 mm, thickness: approx. 5.9 mm

Print on wrapping: (Face) イクスタンジ 80mg, イクスタンジ, 80mg, house-mark, アステラス製薬, (Back) イクスタンジ 80mg, イクスタンジ, 80mg, Xtandi 80mg, house-mark, アステラス製薬



Effects of this medicine

This medicine inhibits binding of androgen (male hormone) against androgen receptors which exist in prostate tissues, and consequently shows anti-tumor effects. It also exerts effectiveness by inhibiting multiple proliferative pathways in prostate cancer cells.

It is usually used for the treatment of castration-resistant prostate cancer and metastatic prostate cancer.

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

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
If you have or have a history of convulsive disease such as epilepsy.
If you have the predisposition to convulsive seizure (having coexisting disease such as brain damage or stroke, or have a history of it).
If you have or have a history of interstitial lung disease.
- 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 2 tablets (160 mg of the active ingredient) at a time, once a day. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. If you miss a dose for a whole day, skip the missed dose and follow your regular dosing schedule from the following day. 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

- In rare cases, this medicine may cause convulsive seizure. Pay attention when you operate dangerous machinery such as driving a car.
- Since this medicine may cause interstitial lung disease, initial symptoms such as shortness of breath, respiratory distress, cough, fever, etc. are checked and chest X-ray and others are performed while using this medicine. If any of these initial symptoms of interstitial lung disease occur, consult with medical institution immediately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, diarrhea, fatigue, asthenia, loss of appetite and hot flush. 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.

- dizziness, shivering, muscle spasm [convulsive seizure]
- nasal bleeding, gum bleeding, subcutaneous bleeding [decreased platelets]
- shortness of breath, respiratory distress, cough, fever [interstitial lung disease]

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. Consult with your dispensing pharmacy or medical institution how to discard.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.