

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

Internal

Revised: 02/2025

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:BICALUTAMIDE TABLETS 80mg 「OHARA」

Active ingredient:Bicalutamide

Dosage form:white tablet, diameter: 7.6 mm, thickness: 4.4 mm

Imprint or print on wrapping:ビカルタミド 80mg「オーハラ」, 80mg, Bicalutamide 80mg
「OHARA」, 1 日 1 回



Effects of this medicine

This medicine inhibits androgen (male hormone) receptor binding to control activities of male hormones. It consequently suppresses cell growth of prostate tumor.

It is usually used in the treatment of prostate cancer.

The following patients may need to be careful when 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 or foods.
If you have hepatic disorder.
- 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 (80 mg of the active ingredient) at a time, once daily. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible when you remember that you missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include breast swelling, breast tenderness, hot flash and erectile dysfunction. 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.

- general malaise, loss of appetite, yellowing in the skin or conjunctiva ocular [fulminant hepatitis, hepatic dysfunction, jaundice]
- throat pain, fever, subcutaneous hemorrhage, submucosal hemorrhage [leukopenia, thrombocytopenia]
- fever, dry cough, breathing difficulty [interstitial pneumonia]

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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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