

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

Internal

Revised: 09/2022

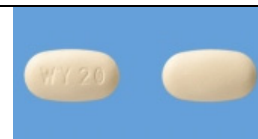
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name: Viviant Tablets 20mg

Active ingredient: Bazedoxifene acetate

Dosage form: pale yellow tablet, major axis: 11.1 mm, minor axis: 6.1 mm, thickness: 5.0 mm

Imprint or print on wrapping: Viviant 20mg, ビビアント 20mg, WY20, 骨粗しょう症の薬(1日1回)



Effects of this medicine

This medicine normalizes bone metabolic imbalance due to depressed secretion of female hormone (estrogen) in postmenopausal women. Consequently, it improves the low bone mass and reduces the risk of bone fracture. It is usually used to treat postmenopausal osteoporosis.

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: venous thromboembolism or its history, antiphospholipid antibody syndrome, a history of hypertriglyceridemia, renal dysfunction or liver dysfunction.
If you are in a long-term bedridden or a similar state, such as after a surgical operation or in a condition that requires long-term rest.
- If you are pregnant, possibly pregnant or breastfeeding.
- 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, take 1 tablet (20 mg of bazedoxifene) at a time, once a day. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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

- Venous thromboembolism may occur. If symptoms such as pain/edema of legs (redness and swelling of one calf, pain on pressing calf, etc.), sudden feeling of respiratory distress, shortness of breath, chest pain or sudden reduced visual acuity/difficulty seeing letters or shapes/abnormal vision, stop taking this medicine and consult with your doctor immediately.
- Because of the increased risk of venous thromboembolism, when you are bedridden or near bedridden for an extended period of time, such as after surgery or during a period of prolonged bed rest, stop taking this medicine after consulting with your doctor and do not resume the use until you are fully able to walk. In addition, consult with your doctor or pharmacist beforehand in case you are intending to be in a state of prolonged immobilization, such as travelling long distances by aircraft or car.
- If you are deficient in calcium or vitamin D, consult with your doctor and supplement with calcium or vitamin D.
- If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, vasodilatation (hot flashes), abdominal pain, thirst, anemia, fibrocystic breast diseases (mastopathy, breast cyst), muscle spasm (muscle stiffness of limbs, cramps of lower limbs), joint pain and tinnitus. 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.

- pain/edema of legs, sudden dyspnea/shortness of breath/chest pain, sudden reduced visual acuity [venous thromboembolism]

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 at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.

•Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, 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.