

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

Internal

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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:**Bepridil Hydrochloride Tablets 50mg "TE"

**Active ingredient:**Bepridil hydrochloride hydrate

**Dosage form:**white tablet with split line, diameter: 6.0 mm, thickness: 3.2 mm

**Imprint or print on wrapping:**ベプリジル, 50mg, 「TE」



**Effects of this medicine**

This medicine improves the symptoms of sustained atrial fibrillation and tachyarrhythmia (with increased pulse rate) by suppressing the abnormal contraction of heart muscle. It also improves angina symptoms by dilating vessels of heart to increase blood flow.

It is usually used to treat sustained atrial fibrillation, tachyarrhythmia (ventricular) and angina.

**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 congestive heart failure, impulse conduction disorder (atrioventricular block or sinoatrial block), sinus bradycardia (slowing of the heart rate) or QT prolongation.
- 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))
  - **Sustained atrial fibrillation:** In general, for adults, start with 1 tablet (50 mg of the active ingredient) at a time, twice a day. If the effect is insufficient, the dosage may be increased up to 2 tablets (100 mg) at a time, twice a day. The dosage may be decreased according to the age or symptoms.
  - **Tachyarrhythmia (ventricular) and angina:** In general, for adults, take 2 tablets (100 mg of the active ingredient) at a time, twice a day. The dosage may be adjusted according to the age or symptoms.
- In any case, strictly follow the instructions.
- Blood test is performed before using this medicine.
  - If you miss a dose, take a dose as soon as possible. If it is almost time for the next dose, 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**

- Periodical tests of electrocardiogram, pulse, blood pressure, cardio-thoracic ratio, etc. are performed while using this medicine. Blood test is also performed if necessary.
- Since interstitial pneumonia may occur while using this medicine (especially within 4 months after starting this medicine), periodical tests including chest X-ray are performed.
- This medicine may cause dizziness. Pay attention to operating dangerous machinery, such as driving a car.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include bradycardia, palpitation, headache, dizziness, lightheadedness, nausea, stomach discomfort, abdominal discomfort, loss of appetite, diarrhea, constipation, heartburn, thirst, rash, malaise, impaired urination, fever, chest discomfort 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.**

- palpitation, shortness of breath, dizziness [QT prolongation, ventricular tachycardia (including Torsade de pointes), ventricular fibrillation, sinus arrest, atrioventricular block]
- fever, sore throat, general malaise [agranulocytosis]
- fever, dry cough, dyspnea [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.