

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

Internal

Revised: 08/2023

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: Cibenol Tablets 100mg

Active ingredient: Cibenzoline succinate

Dosage form: white tablet, diameter: 7.1 mm, thickness: 3.6 mm

Imprint or print on wrapping: (face) シベノール 100mg, (back) シベノール 100, シベンゾリン(Cibenzoline), 100mg, 不整脈治療剤



Effects of this medicine

This medicine normalizes the pulse by blocking the sodium channel (membrane stabilizing activity) of cardiac muscle as well as prolonging the action potential duration.

It is usually used for the treatment of tachyarrhythmia.

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 atrioventricular block, sinoatrial block, congestive heart failure, angle-closure glaucoma or difficulty in urination.
- If you are on dialysis.
- If you are 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, for adults, start with 1 tablet (100 mg as the active ingredient) at a time, 3 times a day. If the effect is insufficient, the dose may be increased up to 1.5 tablets (150 mg) at a time, 3 times a day. The dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.
- If you miss a dose, take the 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

- This medicine may cause dizziness and lightheadedness. Avoid driving a car or operating machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include lightheadedness, thirst and nausea. 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, chest pain, palpitation [proarrhythmic effect]
- pale face, cold sweat, dizziness on standing up [shock, cardiogenic shock, anaphylaxis]
- shortness of breath, general edema, cough [cardiac failure]
- sweating, chills, palpitation [hypoglycemia]
- general malaise, loss of appetite, yellowing of the skin and the whites of eyes [liver disorder due to circulatory failure, hepatic function disorder, jaundice]
- 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 dispose of them, consult with your dispensing pharmacy or medical institution. Do not give this medicine to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.