

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

Internal

Revised: 07/2019

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 (φ : 7.1 mm, thickness: 3.6 mm)

Print on wrapping: (face) シベノール 100mg, (back) シベノール 100, 100mg, シベノゾリン(Cibenzoline)



Effects of this medicine

This medicine works to normalize the pulse by blocking the sodium channel (membrane-stabilizing action) of cardiac muscle as well as prolonging the action potential duration. It is usually used for the treatment of arrhythmia.

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 heart disease, 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 at a dose of 100 mg as the active ingredient at a time, 3 times a day. If it is ineffective, the dose may be increased up to 150 mg at a time, 3 times a day. The dosage may be adjusted according to the patient's age and symptoms. Each tablet contains 100 mg of the active ingredient. Use this tablet when you take the medicine 100 mg at a time according to your dosage described above. Strictly follow the instructions.
- If you miss a dose, take the dose as soon as you realize you have missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule from the next dose onwards. 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

- Dizziness or swaying feeling may occur after taking this medicine. Avoid driving a car, operating machinery or working at heights.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, erythema, feeling of itching, dry mouth, stomach discomfort, and swaying feeling. 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 [arrhythmogenic activity]
- facial pallor, cold sweat, dizziness on standing up [shock, anaphylaxis]
- shortness of breath, whole-body edema, cough [cardiac failure]
- sweat, chills, palpitation [hypoglycemia]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [liver disorder due to circulatory failure, hepatic function disorder, jaundice]
- fever, dry cough, dyspnoea [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 infants and young children. Store away from direct sunlight, heat and humidity.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.