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

Internal Revised: 01/2014

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: Pimobendan Tablets 1.25mg [TE]

Active ingredient:Pimobendan

Dosage form: yellowish white tablet (ϕ : 7.1 mm, thickness: 2.9 mm)

Print on wrapping:(face) ピモベンダン「TE」, 1.25mg, 心不全治療薬, TEC1

(back) ピモベンダン「TE」, 1.25mg, 心不全治療薬



Effects of this medicine

This medicine acts to increase the sensitivity of cardiac muscle to calcium ions and dilate blood vessels by inhibiting phosphodiesterase (PDE-3) activity, thereby improving symptoms such as shortness of breath and difficulty in breathing.

It is usually used for the treatment of acute cardiac failure, chronic cardiac failure (mild to moderate).

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 cardiac disease (myocardial infarction, arrhythmia, etc.), cerebrovascular disorder, liver disorder or renal disorder.
- · 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>>
- For the treatment of acute cardiac failure: In general, for adults, take 2 tablets (2.5 mg as the active ingredient) at a time. Patient may take the dose twice a day depending on the clinical condition. Digitalis preparation, etc. may be used concomitantly as needed basis.

<u>For the treatment of chronic cardiac failure (mild to moderate)</u>: In general, for adults, take 2 tablets (2.5 mg as the active ingredient) at a time, twice a day, after meal. The dosage may be adjusted according to the patient's age and symptoms. Digitalis preparation or diuretic may be used concomitantly.

In any case, strictly follow the instructions.

- •If you miss a dose, take the dose when 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include palpitation, feeling queasy, tachycardia (quickened pulse), hypotension, skin eruption, anemia, and malaise. 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, palpitation, chest pain, chest discomfort [ventricular fibrillation]
- palpitation, short of breath, strange feeling of chest [ventricular tachycardia, ventricular extrasystoles]
- •general malaise, loss of appetite, yellowing of the whites of the eyes [hepatic function disorder, jaundice]

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.

For healthcare professional use only

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