

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:Selara Tablets 50mg

Active ingredient:Eplerenone

Dosage form:pale red tablet, diameter: 7.1 mm, thickness: 4.0 mm

Imprint or print on wrapping:セララ 50mg, Selara50mg, NSR50, 高血圧症・慢性心不全の薬



Effects of this medicine

This medicine inhibits the binding of aldosterone to receptors which are involved in increased blood pressure, heart and vascular fibrosis, heart hypertrophy or ventricular arrhythmia, and consequently shows antihypertensive effects and anti-heart failure effects.

It is usually used to treat hypertension and chronic heart failure (for the patients receiving base treatment such as angiotension converting enzyme inhibitor or angiotensin II receptor antagonist, beta-blocker or diuretic).

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 (itching, rash, etc.) to any medicines or foods.
If you have: hyperkalemia, diabetes mellitus with microalbuminuria or proteinuria, renal dysfunction or liver dysfunction.
- 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 treatment of hypertension: In general, for adults, start with 1 tablet (50 mg of the active ingredient) at a time, once a day. If it is not effective enough, the dosage may be increased up to 2 tablets (100 mg) per day. However, if you take this medicine in combination with other medicinal products that suppress its metabolism, the daily dosage may not exceed 25 mg at a time, once a day.
For treatment of chronic heart failure: In general, for adults, start with 25 mg of the active ingredient at a time, once a day. After 4 weeks from the start as a guide, the dosage may be increased to 50 mg at a time, once a day according to the serum potassium level or conditions. However, if you have moderate renal dysfunction, start with 25 mg at a time, once every other day. The maximum daily dose is 25 mg at a time, once a day, but the dosage may be decreased or this medicine may be discontinued according to the serum potassium level or conditions. If you take this medicine in combination with other medicinal products that suppress its metabolism, the daily dosage may not exceed 25 mg at a time, once a day.
This preparation contains 50 mg of the active ingredient in a tablet. In any case, strictly follow the instructions.
- If you miss a dose and remember it within one day, take the missed dose when you remember. 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

- Since this medicine may cause dizziness by declining blood pressure, pay close attention to operating dangerous machinery, such as driving a car or working at heights.
- Avoid taking any health supplement containing St. John's wort (a kind of herb) with this medicine, since it may enhance the metabolism of this medicine and diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, dizziness, nausea, fatigue, hypotension, renal dysfunction, indigestion and muscle cramp. 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.

- numbness of limbs or lips, muscle weakness, paralysis of limbs [hyperkalemia]

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 away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.