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

Internal
Revised: 02/2024

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:Entresto Tablets 50 mg

Active ingredient: Sacubitril valsartan sodium hydrate
Dosage form:blueish purple white oval tablet, major axis: 13.1 mm, minor axis: 5.2 mm, thickness: 3.6 mm
Imprint or print on wrapping:エンレスト 50 mg, Entresto 50 mg, NVR LZ

Effects of this medicine

This medicine suppresses the actions of substances called neprilysin and angiotensin II to lower blood pressure, reduce the amount of water stored in the body, reduce the burden on the heart, and prevent worsening of heart failure.
It is usually used to treat chronic heart failure.

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 renal artery stenosis, hyperkalemia, cerebrovascular disorder, renal dysfunction, hepatic dysfunction, hypotension, a history of angioedema, or schedule of surgery.
・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))
・[for adults] In general, for adults, take 50 mg of sacubitril valsartan at a time, twice a day as the initial dose. The dosage may be increased up to 200 mg at intervals of 2 to 4 weeks in a stepwise manner if the adverse reactions do not interfere with the treatment. The dose is 50 mg, 100 mg or 200 mg at a time. The dosage may be adjusted according to the tolerability.
[for children] In general, for children aged 1 year or older, take sacubitril valsartan at the starting dose based on body weight (details are described below) twice daily. If tolerated, the dose may be gradually increased to the target dose at 2 to 4 weeks intervals. The dosage may be adjusted according to tolerability.
=Details of dosage for children (single dose)=
The starting dose per administration based on body weight is 0.8 mg/kg for under 40 kg, 0.8 mg/kg for 40 kg or over but under 50 kg, and 50 mg for over 50 kg. The first ascending dose will be 1.6 mg/kg for under 40 kg, 50 mg for 40 kg or over but under 50 kg, and 100 mg for over 50 kg. The second ascending dose will be 2.3 mg/kg for under 40 kg, 100 mg for 40 kg or over but under 50 kg, and 150 mg for over 50 kg. The target dose is 3.1 mg/kg for under 40 kg, 150 mg for 40 kg or over but under 50 kg, and 200 mg for over 50 kg.
The starting dose may be started with the first ascending dose depending on your previous treatment history and condition.
*For Children, prepared syrup (suspension) may be given.
*Each tablet of this medicine contains 50 mg of sacubitril valsartan. Strictly follow the instructions.
・If you miss a dose, take a dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue 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 or lightheadedness. Pay close attention when you work at heights, drive a car or operate machinery.
・This medicine has been reported to be teratogenic (may cause malformations in fetuses), women of childbearing potential should avoid pregnancy by using a reliable contraceptive method while using this medicine and for 1 week after the discontinuation of this medicine. So if you suspect that you are pregnant, contact your doctor immediately.
・It is recommended not to breastfeed while taking this medicine. If you are breastfeeding, consult with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypotension and renal impairment. 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.

- swelling of eyelids, lips and/or tongue, difficulty swallowing or breathing (due to edema of the airway) [angioedema]
- general malaise, dizziness, lightheadedness [hypotension]
- numbness of limbs or lips, muscle weakness, paralysis of arm/legs [hyperkalemia]
- cold sweat, pale face, losing consciousness [shock, syncope, unconsciousness]
- decrease urine output, edema, loss of appetite [renal impairment, renal failure]

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 are not sure how to discard, consult with your pharmacist or medical institution. Do not give it to anyone else.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.