

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

Internal

Revised: 12/2023

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: Evrenzo Tablets 20mg

Active ingredient: Roxadustat

Dosage form: pale yellowish red tablet, diameter: approx. 5.6 mm, thickness: approx. 3.0 mm

Imprint or print on wrapping: エベレンゾ錠 20mg, 腎性貧血治療薬, お薬をのむ日, house-mark, 週3回のむお薬です, 毎日のむお薬ではありません, Evrenzo, アステラス製薬



Effects of this medicine

This medicine activates hypoxia inducible factor (HIF) pathways by inhibiting HIF prolyl hydroxylase (HIF-PH) causing degradation of HIF, and boosts hematopoietic factor (erythropoietin) which promotes red blood cell production to increase the number of red blood cells. It consequently improves anemia attributable to renal diseases. It is usually used to treat renal anemia.

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 or have a history of cerebral infarction, myocardial infarction or pulmonary embolism.
If you have: hypertension, malignant tumor, proliferative diabetic retinopathy, macular edema, exudative age-related macular degeneration, retinal vein occlusion or liver dysfunction.
- 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 patients untreated by erythropoiesis stimulating agent: In general, for adults, start taking this medicine with 50 mg of the active ingredient at a time, 3 times a week. Thereafter, the dosage may be adjusted according to the condition of the patient. The maximum single dose is 3.0 mg/kg.
For patients switching from erythropoiesis stimulating agent: In general, for adults, start taking this medicine with either 70 mg or 100 mg of the active ingredient at a time, 3 times a week. Thereafter, the dosage may be adjusted according to the condition of the patient. The maximum single dose is 3.0 mg/kg.
This medicine contains 20 mg of the active ingredient in a tablet. In any case, strictly follow the instructions.
- Take this medicine 3 times a week, at intervals of 2 to 3 days (e.g. on Monday/Wednesday/Friday or on Tuesday/Thursday/Saturday).
- Anemia test (measuring hemoglobin concentration) will be performed before using this medicine.
- If you miss a dose and there are 24 hours or more until the next scheduled dose, take the missed dose as soon as possible and follow your regular dosing schedule thereafter. However, if there are less than 24 hours remaining, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time in the same day.
- 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

- If any symptoms such as sudden paralysis on one side of the limbs or face, numbness, headache, speech difficulties, vision disturbance, consciousness disorder, acute pressure in anterior chest, anginal pain, cold sweat, dyspnea, cough or fever occur, get immediate medical attention.
- Hypertension may occur when using this medicine.
- To measure serum concentrations of hemoglobin, blood tests will be periodically performed while using this medicine.
- Since central hypothyroidism may occur, thyroid function tests (TSH, Free T3, Free T4) will be periodically performed while using this medicine.
- You need to take iron to get an adequate efficacy. If you are prescribed iron preparation, you should take it as instructed by your doctor.
- If you have a possibility of pregnancy, use adequate contraception while you are taking this medicine and for a certain period of time after the last dose of this medicine.
- Lactate transfer has been reported in animal experiments. Avoid breastfeeding from the start to 28 days after the last dose of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include vomiting, diarrhea, constipation and hypertension. 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.

- local pain or swelling, chest pain, breathing difficulty [thromboembolism]
- muscle spasmodically contracting [convulsive seizure]
- malaise, intolerance to cold, lack of motivation [central hypothyroidism]

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 at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.