

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: Tracleer 32mg Dispersible Tablets for Pediatric

Active ingredient: Bosentan hydrate

Dosage form: white tablet, major axis: 10 mm, thickness: 3.4 mm

Print on wrapping:トラグリア小児用分散錠 32mg



Effects of this medicine

This medicine suppresses the function of endothelin, an artery contraction substance, to lower pulmonary arterial blood pressure.

It is usually used to treat pulmonary arterial hypertension.

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 liver dysfunction or hypotension.
- 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))
- In general, for babies, infants and children, give 2 mg/kg of bosentan at a time, twice a day in the morning and evening as needed. Disperse the medicine in small amount of water and give it. The maximum single dose and maximum daily dose are 120 mg (3 and 3/4 tablets) at a time and 240 mg (7 and 1/2 tablets) a day, respectively. Strictly follow the instructions.
- If you miss a dose, you should never take two doses at one time. Take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule.
- If you accidentally take more than your prescribed dose, severe reduction in blood pressure may occur. If you feel abnormality, 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 decrease the effect of oral contraceptive during medication. Avoid using oral contraceptive alone for contraception, but use a different contraception method in combination. If you have a possibility of pregnancy, make sure to take a pregnancy test every month before and during medication.
- Since this medicine may impair the function of the liver, monthly liver function test is performed before and during medication. It is considered that the test should be taken every 2 weeks for the first 3 months of medication. Please keep all your appointments.
- Since this medicine may cause anemia and decreased platelets, you should receive a blood test every month before and for the first 4 months of medication, and every 3 months thereafter.
- If you have heart disease and gained weight suddenly, heart failure is suspected. In such a case, consult with your doctor or pharmacist.
- Refrain from taking grapefruit juice and any food containing St. John's wort, since the effect of this medicine may be affected.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nasal congestion, abdominal pain, chest pain, flush and headache. 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.

- malaise, loss of appetite, vomiting [serious liver dysfunction]
- dizziness, bleeding tendency, sore throat [pancytopenia, decreased white blood cells, decreased neutrophils, decreased platelets, anemia]
- sudden weight gain, shortness of breath, palpitation [heart failure, congestive heart 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.

- Store split tablet pieces in a closed container (can with a lid or zippered poly bag) at room temperature. Take it within 7 days under the instructions of your doctor.
- Discard the remainder. Do not store them. Ask the pharmacist and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.